

EPA Reg. No. 83416-1
Vol. 1
Part 3

SAFETY DATA SHEET

Date: 03-26-2014

1. IDENTIFICATION

Product identity: Mixture of mono-potassium phosphite and di-potassium phosphite

Manufactured by

QUEST Products LLC.

11712 230th St

Linwood, KS 66052 Phone -785-542-2577 Fax 785-542-2531

Emergency phone numbers

NPC (National Poison Control Hotline): 800-222-1222

NPIC (National Pesticide Information Center): 800-858-7378

EPA National Response Center: 800-424-8802

2. HAZARD(S) IDENTIFICATION

The components of this product, mono-potassium phosphite (CAS No. 13977-65-6) and di-potassium phosphite (CAS No. 13492-26-7) are not classified as hazardous under The Hazard Communication Standard (29 CFR 1910.1200).

3. COMPOSITION/INFORMATION ON INGREDIENTS

Mixture of mono-potassium phosphite (CAS No. 13977-65-6) and di-potassium phosphite (CAS No. 13492-26-7) @ 45.8%

4. FIRST AID

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice
- Have person sip a glass of water if able to swallow
- Do not induce vomiting unless told to do so by a poison control center or doctor
- Do not give anything by mouth to an unconscious person

IF IN EYES:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye
- Call poison control center or doctor for treatment advice

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IF ON SKIN OR CLOTHING:

- Take off contaminated clothing
- Rinse skin immediately with plenty of water for 15-20 minutes
- Call a poison control center or doctor for treatment advice

IF INHALED:

- Move person to fresh air
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible
- Call a poison control center or doctor for further treatment advice

Have the product container or label with you when calling a poison control center or doctor or going for treatment.

5. FIRE FIGHTING MEASURES

Flash Point:	Not applicable.
Test method:	Not available.
LEL flammable limits:	Not available.
UEL flammable limits:	Not available.
Autoignition temperature:	Not available.
Flammability classification:	Not applicable.
Known hazardous products of combustion:	None
that initiate/contribute to intensity of fire:	None
Potential for dust explosion:	None
Reactions that release flammable gases or vapors:	Not known.
Potential for release of flammable vapors:	Not known.

Unusual fire and explosion hazards: This is not a flammable material. Some gases such as phosphorus oxides may be released.

Extinguishing media: Carbon dioxide, dry chemical, foam, water spray. Special firefighting procedures: Use full-faced self-contained breathing apparatus along with full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Containment:	Prevent product from spilling and entering drinking water supplies or streams.
Clean up:	Collect liquid or absorb onto absorbent material and package for disposal.
Evacuation:	Not necessary.

7. HANDLING AND STORAGE

- Storage:** Store in a well sealed container in a cool, well- ventilated, dry place at temperatures above 40°F. Do not store near combustible materials, herbicides, fungicides, and food or feeds. Do not stack pallets more than two (2) high.
- Transfer equipment:** Transfer product using chemical-resistant plastic or stainless steel tanks, pumps, valves, etc.
- Work/hygienic practices:** Keep out of reach of children. May be harmful if swallowed, inhaled or absorbed through the skin. Avoid breathing vapors or spray mist. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse. Do not allow children or pets to contact treated area until spray dries.

8. EXPOSURE CONTROLS/PERSONAL PROTECTIVE EQUIPMENT

- Eye:** Chemical dust/splash goggles or full-face shield to prevent eye contact. As a general rule, do not wear contact lenses when handling.
- Skin:** Long-sleeved shirt, long pants, shoes, socks and household latex or rubber gloves.
- Respiratory:** Not normally needed. If use generates an aerosol mist or respiratory irritation, use NIOSH approved dust/mist respirator (such as 3M #8710).
- Ventilation:** Use in well ventilated area but no TLV established.

9. PHYSICAL AND CHEMICAL PROPERTIES

- | | |
|--------------------------|-----------------|
| Appearance: | Blue liquid. |
| Odor: | Slight to none. |
| pH: | 5.72 @ 20°C |
| Vapor pressure: | Not available. |
| Vapor density: | Not available. |
| Boiling point: | 105°F |
| Freezing point: | Not available. |
| Water solubility: | Miscible. |
| Density: | 1.37g/mL |

Evaporation rate:	Not available.
Viscosity:	2.273 (cSt) @ 20°C.
% Volatile:	Not available.
Octanol/water partition coefficient:	Not available.

10. STABILITY AND REACTIVITY

Stability:	Stable.
Conditions to avoid:	Avoid strong oxidizers and bases. Corrosive to most metals.
Incompatibility:	Not compatible with strong oxidizers, bases and most metals.
Hazardous decomposition products:	Gases of phosphorus oxides

11. TOXICOLOGICAL INFORMATION

Acute effects:

Ingestion:	Ingestion may cause diarrhea, nausea, vomiting, and cramps.
Eyes:	Mild irritant to eyes. Skin: Mildly irritating to skin.
Inhalation:	May be slightly irritating.
<u>Subchronic effects:</u>	None known.
<u>Chronic effects:</u>	Not established.

12. ECOLOGICAL INFORMATION

Algal/Lemna growth inhibition:	Not known.
Toxicity to fish (rainbow trout):	> 100mg/L.
Toxicity to plants:	Not known.
Toxicity to birds:	Not known.

13. DISPOSAL CONSIDERATIONS

Do not contaminate lakes, streams, ponds, estuaries, oceans, or other waters by discharge of waste effluents or equipment washwaters.

If container is empty: do not reuse this container. Place in trash or offer for recycling.

If container is partially filled: call your local solid waste agency or 1-800- CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

7. HANDLING AND STORAGE

- Storage:** Store in a well sealed container in a cool, well-ventilated, dry place at temperatures above 40°F. Do not store near combustible materials, herbicides, fungicides, and food or feeds. Do not stack pallets more than two (2) high.
- Transfer equipment:** Transfer product using chemical-resistant plastic or stainless steel tanks, pumps, valves, etc.
- Work/hygienic practices:** Keep out of reach of children. May be harmful if swallowed, inhaled or absorbed through the skin. Avoid breathing vapors or spray mist. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse. Do not allow children or pets to contact treated area until spray dries.

8. EXPOSURE CONTROLS/PERSONAL PROTECTIVE EQUIPMENT

- Eye:** Chemical dust/splash goggles or full-face shield to prevent eye contact. As a general rule, do not wear contact lenses when handling.
- Skin:** Long-sleeved shirt, long pants, shoes, socks and household latex or rubber gloves.
- Respiratory:** Not normally needed. If use generates an aerosol mist or respiratory irritation, use NIOSH approved dust/mist respirator (such as 3M #8710).
- Ventilation:** Use in well ventilated area but no TLV established.

9. PHYSICAL AND CHEMICAL PROPERTIES

- | | |
|--------------------------|-----------------|
| Appearance: | Blue liquid. |
| Odor: | Slight to none. |
| pH: | 5.72 @ 20°C |
| Vapor pressure: | Not available. |
| Vapor density: | Not available. |
| Boiling point: | 105°F |
| Freezing point: | Not available. |
| Water solubility: | Miscible. |
| Density: | 1.37g/mL |

Version: 03-26-2014

14. TRANSPORT INFORMATION

DOT (domestic surface)

Hazard class or division:

Non-regulated

Other shipping description:

Fertilizers, liquid.

15. REGULATORY INFORMATION

CERCLA: None.

Proposition 65: None

SARA Information: SARA TITLE III; SEC. 311/312 HAZARD CATEGORIES

Immediate (Acute) Health: Yes

Sudden Release of Pressure: No

Delayed (Chronic) Health: No

Reactivity: No

Fire: No

SARA TITLE III-SEC. 313 SUPPLIER NOTIFICATION: None

NFPA: HEALTH: 1

REACTIVITY: 0

FLAMMABILITY: 0

ENVIRONMENT: 0

(0=Insignificant 1=Slight 2=Moderate 3=High 4=Extreme)

16. OTHER INFORMATION

All information appearing in this document was based on data provided by third party sources and was compiled to comply with the Federal Hazard Communication Standard and the California Hazardous Substances Information and Training Act. The information is believed to be accurate as of the preparation date, but is not warranted as being the final authority in the use of this product. This information does not purport to be legal or medical advice.

MATERIAL SAFETY DATA SHEET**RELIANT® Systemic Fungicide**

Revised 01-090-12

1. PRODUCT AND COMPANY IDENTIFICATION

Product identity: **RELIANT® Systemic Fungicide**
 EPA Registration No.: **83416-1**

Manufactured by

QUEST Products LLC.
11712 230th St
Linwood, KS 66052 Phone -785-542-2577 Fax 785-542-2531

Common name: Liquid systemic fungicide
 Chemical description: Mono- and di-potassium salts of phosphorus acid
 TSCA/CAS No.: This product is a mixture of CAS No. 13977-65-6 and CAS No. 13492-26-7

Emergency phone numbers

NPC (National Poison Control Hotline): 800-222-1222
NPIC (National Pesticide Information Center): 800-858-7378
EPA National Response Center: 800-424-8802

2. HAZARDOUS INGREDIENTS

Chemical	CAS Number	%	TLV or PEL	LD ₅₀ (lbs)
None				

3. EMERGENCY/HAZARDS OVERVIEW

Blue liquid with slight to no odor. Harmful if swallowed, inhaled or absorbed through the skin. Avoid breathing vapors or spray mist. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Avoid strong oxidizing agents and strong bases. Corrosive to most metals. Not DOT regulated.

HEALTH: 2 RACTIVITY: 0 FLAMMABILITY: 0 ENVIRONMENT: 0
 (0= Insignificant 1= Slight 2= Moderate 3= High 4= Extreme)

4. FIRST AID**IF SWALLOWED:**

- Call a poison control center or doctor immediately for treatment advice
- Have person sip a glass of water if able to swallow

- Do not induce vomiting unless told to do so by a poison control center or doctor
- Do not give anything by mouth to an unconscious person

IF IN EYES:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye
- Call poison control center or doctor for treatment advice

IF ON SKIN OR CLOTHING:

- Take off contaminated clothing
- Rinse skin immediately with plenty of water for 15-20 minutes
- Call a poison control center or doctor for treatment advice

IF INHALED:

- Move person to fresh air
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible
- Call a poison control center or doctor for further treatment advice

Have the product container or label with you when calling a poison control center or doctor or going for treatment.

5. FIRE FIGHTING MEASURES

Flash Point:	Not applicable.
Test method:	Not available.
LEL flammable limits:	Not available.
UEL flammable limits:	Not available.
Autoignition temperature:	Not available.
Flammability classification:	Not applicable.
Known hazardous products of combustion:	None
Properties that initiate/contribute to intensity of fire:	None
Potential for dust explosion:	None
Reactions that release flammable gases or vapors:	Not known.
Potential for release of flammable vapors:	Not known.
Unusual fire and explosion hazards:	This is not a flammable material. Some gases such as phosphorus oxides may be released.

Extinguishing media: Carbon dioxide, dry chemical, foam, water spray.

Special firefighting procedures: Use full-faced self-contained breathing apparatus along with full protective gear.

6. ACCIDENTAL RELEASE MEASURES

- Containment:** Prevent product from spilling and entering drinking water supplies or streams.
- Clean up:** Collect liquid or absorb onto absorbent material and package for disposal.
- Evacuation:** Not necessary.

7. HANDLING AND STORAGE

- Storage:** Store in a well sealed container in a cool, well-ventilated, dry place at temperatures above 40°F. Do not store near combustible materials, herbicides, fungicides, and food or feeds. Do not stack pallets more than two (2) high.
- Transfer equipment:** Transfer product using chemical-resistant plastic or stainless steel tanks, pumps, valves, etc.
- Work/hygienic practices:** Keep out of reach of children. May be harmful if swallowed, inhaled or absorbed through the skin. Avoid breathing vapors or spray mist. Causes moderate eye irritation. Avoid contact with eyes, skin of clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse. Do not allow children or pets to contact treated area until spray dries.

8. PERSONAL PROTECTIVE EQUIPMENT

- Eye:** Chemical dust/splash goggles or full-face shield to prevent eye contact. As a general rule, do not wear contact lenses when handling.
- Skin:** Long-sleeved shirt, long pants, shoes, socks and household latex or rubber gloves.
- Respiratory:** Not normally needed. If use generates an aerosol mist or respiratory irritation, use NIOSH approved dust/mist respirator (such as 3M #8710).
- Ventilation:** Use in well ventilated area but no TLV established.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Blue liquid.
Odor:	Slight to none.
pH:	5.5 @ 20°C
Vapor pressure:	Not available.
Vapor density:	Not available.
Boiling point:	105°F
Freezing point:	Not available.
Water solubility:	Miscible.
Density:	11.36 lbs/gallon.
Evaporation rate:	Not available.
Viscosity:	2.273 (cSt) @ 20°C.
% Volatile:	Not available.
Octanol/water partition coefficient:	Not available.

10. STABILITY AND REACTIVITY

Stability:	Stable.
Conditions to avoid:	Avoid strong oxidizers and bases. Corrosive to most metals.
Incompatibility:	Not compatible with strong oxidizers, bases and most metals.
Hazardous decomposition products:	None known.
Hazardous polymerization:	Will not occur.

11. TOXICOLOGICAL INFORMATION

<u>Acute effects:</u>	
Ingestion:	Ingestion may cause diarrhea, nausea, vomiting, and cramps.
Eyes:	Mild irritant to eyes.
Skin:	Mildly irritating to skin.
Inhalation:	May be slightly irritating.
<u>Subchronic effects:</u>	None known.
<u>Chronic effects:</u>	Not established.

12. ECOLOGICAL INFORMATION

Algal/Lemna growth inhibition:	Not known.
Toxicity to fish (rainbow trout):	> 100mg/L.
Toxicity to plants:	Not known.
Toxicity to birds:	Not known.

13. DISPOSAL CONSIDERATIONS

Do not contaminate lakes, streams, ponds, estuaries, oceans, or other waters by discharge of waste effluents or equipment washwaters.

If container is empty: do not reuse this container. Place in trash or offer for recycling.

If container is partially filled: call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

14. TRANSPORT INFORMATION

DOT (domestic surface)

Hazard class or division: Non-regulated

Other shipping description:

Insecticides or fungicides, liquid.
NMFC Item 102120, LTL Class 60

15. REGULATORY INFORMATION

CERCLA: None.

SARA TITLE III, Section 311 toxic chemicals: None

Proposition 65: None

16. OTHER INFORMATION

All information appearing in this document was based on data provided by third party sources and was compiled to comply with the Federal Hazard Communication Standard and the California Hazardous Substances Information and Training Act. The information is believed to be accurate as of the preparation date, but is not warranted as being the final authority in the use of this product. This information does not purport to be legal or medical advice.

RELIANT® is a registered trademark of Quest Products Corp.

DATA PACKAGE BEAN SHEET

Date: 24-Mar-2014

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Decision #: 483282

DP #: (418750)

PRIA

Parent DP #:

Submission #: 949355

E-Sub #:

*** Registration Information ***

Registration: **83416-1 - RELIANT SYSTEMIC FUNGICIDE**

Company: 83416 - QUEST PRODUCTS L.L.C.

Risk Manager: RM 91 - Andrew Bryceland - (703) 308-6928 Room# PY1 S-8873

Risk Manager Reviewer: Gina Burnett GBURNETT

Sent Date: _____

PRIA Due Date: 19-May-2014

Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (B681) AMENDMENT; UNREGISTERED SOURCE OF ACTIVE INGREDIENT; REQUIRES DATA

Ingredients: 076416, Mono- and di- potassium salts of phosphorous acid(45.8%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 24-Mar-2014

Due Back: _____

DP Ingredient: 076416, Mono- and di- potassium salts of phosphorous acid

DP Title: _____

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #: _____

Assigned To

Date In

Date Out

Organization: BPPD / BPB

Last Possible Science Due Date: 20-Nov-2013

Team Name: RM 91

Science Due Date: _____

Reviewer Name: Fuentes, Clara

Sub Data Package Due Date: _____

Contractor Name: _____

*** Studies Sent for Review ***

No Studies

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

Clara,

Please review this resubmission and let me know if any issues remain.

Thanks!

Gina

Review due date: asap or March 28, 2014

PRIA due date: May 19, 2014 (expedite per Linda)

Burnett, Gina

From: Bill Stringfellow Quest <bill@questproducts.us>
Sent: Wednesday, March 19, 2014 11:27 AM
To: Hollis, Linda; Leahy, John; Robert EPA regulatory
Cc: Bryceland, Andrew; Cole, Leonard S.; McNally, Robert; Burnett, Gina
Subject: Re: Reliant Systemic Fungicide EPA.No 83416-1 submission

Importance: High

Follow Up Flag: Follow up
Flag Status: Completed

Ms. Hollis,

Per our telephone conversation this morning on the Reliant Systemic Fungicide EPA No.83416-1 submission.

We will forgo the submitted label modifications and amendment for additional uses submitted Sept. 11, 2013 and return the to original approved label of March 22, 2012, that will be submitted in the front end package by Robert Rosenwasser on March 20 and courtesy electronic copy sent today.

This with the understanding that review of the Product Chemistry can be expedited and a letter of conditional approval be issued by March 28, 2014 so that production can resume to satisfy and quell grower/end-user demand. If at all possible could this approval document be electronically transmitted to us to save additional time from standard mail service.

We understand the work load of accomplishing this task large but if within your powers meet our March 28th date.

Thank you for time and effort in expediting this action.

Regards,

Bill Stringfellow

From: Hollis, Linda
Sent: Wednesday, March 19, 2014 8:56 AM
To: Bill Stringfellow Quest ; Leahy, John ; Robert EPA regulatory
Cc: Bryceland, Andrew ; Cole, Leonard S. ; McNally, Robert ; Burnett, Gina
Subject: Re: Reliant Systemic Fungicide EPA.No 83416-1 submission

Correction. My 10am has been canceled and I am available to take your call if you need to discuss the matter any further. If not, per your voice mail, we await the resubmitted materials that will be sent electronically and through the document processing center.

From: Hollis, Linda
Sent: Wednesday, March 19, 2014 9:48:44 AM
To: Bill Stringfellow Quest; Leahy, John; Robert EPA regulatory
Cc: Bryceland, Andrew; Cole, Leonard S.; McNally, Robert; Burnett, Gina
Subject: Re: Reliant Systemic Fungicide EPA.No 83416-1 submission

Thank you. I am in receipt of your voice mail of yesterday. I am currently in the office but have scheduled meetings at 10am, 12noon, 1:30 and 3pm.

Please note that we will do all that we can to move swiftly to review the information, conduct a label review and render a regulatory decision. I understand the urgent need for this product as you have been without supply for some time. Having said that, I am unable to offer to you an exact date prior to the scheduled PRIA date as to when your action will be completed. I can reiterate the fact that I will do all that I can to help move it along quickly.

Regards,

Linda Hollis

From: Bill Stringfellow Quest <bill@questproducts.us>
Sent: Wednesday, March 19, 2014 9:17:44 AM
To: Hollis, Linda; Leahy, John; Robert EPA regulatory
Cc: Bryceland, Andrew; Cole, Leonard S.; McNally, Robert; Burnett, Gina
Subject: Re: Reliant Systemic Fungicide EPA.No 83416-1 submission

Ms. Hollis,

Appreciate you, and your staffs quick response on this pressing matter.

Robert Rosenwasser will be submitting all the items that you have identified as needing additional attention for completion electronically immediately and by hardcopy through the document processing center. These documents should arrive at document processing by Thursday March 20th.

I would like to follow up with you with a short telephone call this morning if at all possible to discuss moving forward with approval of the chemistry review section after your staff has had an opportunity to review the additional documentations correctness. This in order to relieve the tremendous pressure being put upon us from the grower/end user/applicator community that is spilling over onto EPA.

Thank you for you diligence in resolving this matter.

Regards,

Bill Stringfellow

From: Hollis, Linda
Sent: Tuesday, March 18, 2014 3:37 PM
To: Leahy, John ; Bill Stringfellow Quest
Cc: Bryceland, Andrew ; Cole, Leonard S. ; McNally, Robert ; Burnett, Gina
Subject: RE: Reliant Systemic Fungicide EPA.No 83416-1 submission

Dear Mr. Stringfellow:

I have consulted with counsel and it has been determined that your request to the change the source of your originally repacked registration by adding an unregistered source can be achieved via a label amendment to the existing product and there is no need to establish a new product. As such, your product can be amended by the

PRIA due date of 5/19/14, provided you address the remaining issues and they are deemed acceptable by the agency. In sum, we have conducted a review of the materials that you submitted electronically and received by EPA on Friday, Marcy 14, 2014. Based on our review of the courtesy information, we have the following comments/questions.

- 1) Corrosion Characteristics have not been addressed. The applicant can easily address this data requirement during their ongoing Storage Stability study. The applicant must update MRID 492168-02 to reflect that both the Storage Stability and the Corrosion Characteristics studies are ongoing.
- 2) The MSDS submitted for the active ingredients are not from the company listed as "Supplier" in box 11 of the "post reaction" Alternate and Basic Formulation CSFs. The applicant needs to correct the Supplier name on these CSFs, or submit the correct MSDS for the active ingredients in their product.
- 3) The submitted "pre-reaction" and "post-reaction" CSFs do not seem to correspond in composition – that is, there are no inert ingredients listed on the "pre-reaction" CSF. The applicant must clarify the purpose of this CSF. Is this just describing the manufacturing process of the active ingredient?
- 4) We are confused as to if this Alternate Formulation CSF, dated 8/30/2013, is intended to be identical to the Basic CSF dated 3/9/2014 that was recently submitted. Was the "Alternate Formulation" designation a typo in the original submission? These CSFs are identical. The applicant must clarify if there is supposed to be more than one formulation.

Please provide a response to the above comments. Once we are in receipt of your response and have determined that the data are complete, we will conduct a label review. Please also provide an official copy of your response through the document processing center.

Regards,

Linda A. Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division

From: Leahy, John
Sent: Tuesday, March 18, 2014 12:44 PM
To: Bill Stringfellow Quest; Hollis, Linda
Cc: Bryceland, Andrew; Cole, Leonard S.; McNally, Robert
Subject: RE: Reliant Systemic Fungicide EPA.No 83416-1 submission

Mr. Stringfellow,

I received your voice message and have checked-in with Linda. She is actively following up on this and expects to be back in touch with you later today on the path forward. Feel free to call or send email if there are still outstanding issues after you hear from Linda. Thanks,

John Leahy

From: Bill Stringfellow Quest [<mailto:bill@questproducts.us>]
Sent: Monday, March 17, 2014 4:36 PM
To: Hollis, Linda; Leahy, John

Cc: Bryceland, Andrew; Cole, Leonard S.; McNally, Robert
Subject: Reliant Systemic Fungicide EPA.No 83416-1 submission
Importance: High

Ms. Hollis:

Thank you for discussing over the telephone last Friday our application to amend EPA Reg. No. 83416-1. As outlined below, we request BPPD to approve our pending application to amend our end use ("EP") product that we intend to produce using an integrated system. We believe all of the necessary reviews have been completed by BPPD. We respectfully submit that submitting a new application at this juncture to register a manufacturing use product ("MUP") for incorporation into our EP is neither necessary, cost-effective or consistent with our business plans. As you are aware, we are under significant continuing pressure from the end user community to supply our Reliant Systemic Fungicide product this spring.

Quest Products explained to BPPD in writing from the outset our registration intentions – specifically, to amend our existing registration to permit the production of our EP from an integrated process, as expressly permitted by 40 C.F.R. § 158.325(b). Our original submission cover letter dated Sept. 11, 2013 clearly set forth how and who assisted in its development from BPPD. We requested that BPPD expedite and complete its review of the chemistry section of our application by March 15, 2014 because we are without source of supply, and because we are facing demands from growers for a product that will aid in preventing the loss of trees from disease this spring.

BPPD has completed the front end primary screen of our application package. It completed its technical review, chemistry review and data matrix review as of February 4, 2014, subject to our making some minor additions and correction, which we have addressed or are in process of sending to the reviewer. In summary, BPPD has completed all of the elements for a PRIA code B-681, and we request that, subject to our submitting the last piece of information, BPPD approve our registration. We have completed all of the product chemistry requirements to enable BPPD to approve an EPA produced from an integrated system. 40 C.F.R. § 158.325(b). Moreover, OPP policy clearly permits its divisions to amend an EPA registration from a repack to an integrated process.

While we would hope that you would agree that we have complied with the letter of EPA's regulations, if necessary, we are pleased to confirm our original meeting date of Thursday March 20th at 11:00 a.m. as previously arranged by Andrew Bryceland with you, members of your team and Assistant Director John Leahy. The purpose of this meeting would to understand from BPPD and OPP why our application is deficient in the context of § 158.325(b) so we, in turn, can explain to growers/end users why we are unable to meet their demands this spring for our product which is intended to prevent the loss of trees from disease.

Thank you for your assistance in this matter. I would appreciate your e-mailing me tomorrow to advise me if it will be necessary for me to travel to Washington to meet with you or Thursday or whether this matter can be resolved without a meeting.

Sincerely,

William Stringfellow

Burnett, Gina

From: Hollis, Linda
Sent: Tuesday, March 18, 2014 4:37 PM
To: Leahy, John; Bill Stringfellow Quest
Cc: Bryceland, Andrew; Cole, Leonard S.; McNally, Robert; Burnett, Gina
Subject: RE: Reliant Systemic Fungicide EPA.No 83416-1 submission

Dear Mr. Stringfellow:

I have consulted with counsel and it has been determined that your request to change the source of your originally repacked registration by adding an unregistered source can be achieved via a label amendment to the existing product and there is no need to establish a new product. As such, your product can be amended by the PRIA due date of 5/19/14, provided you address the remaining issues and they are deemed acceptable by the agency. In sum, we have conducted a review of the materials that you submitted electronically and received by EPA on Friday, March 14, 2014. Based on our review of the courtesy information, we have the following comments/questions.

- 1) Corrosion Characteristics have not been addressed. The applicant can easily address this data requirement during their ongoing Storage Stability study. The applicant must update MRID 492168-02 to reflect that both the Storage Stability and the Corrosion Characteristics studies are ongoing.
- 2) The MSDS submitted for the active ingredients are not from the company listed as "Supplier" in box 11 of the "post reaction" Alternate and Basic Formulation CSFs. The applicant needs to correct the Supplier name on these CSFs, or submit the correct MSDS for the active ingredients in their product.
- 3) The submitted "pre-reaction" and "post-reaction" CSFs do not seem to correspond in composition – that is, there are no inert ingredients listed on the "pre-reaction" CSF. The applicant must clarify the purpose of this CSF. Is this just describing the manufacturing process of the active ingredient?
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Please provide a response to the above comments. Once we are in receipt of your response and have determined that the data are complete, we will conduct a label review. Please also provide an official copy of your response through the document processing center.

Regards,

Linda A. Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division

From: Leahy, John
Sent: Tuesday, March 18, 2014 12:44 PM
To: Bill Stringfellow Quest; Hollis, Linda

Cc: Bryceland, Andrew; Cole, Leonard S.; McNally, Robert
Subject: RE: Reliant Systemic Fungicide EPA.No 83416-1 submission

Mr. Stringfellow,

I received your voice message and have checked-in with Linda. She is actively following up on this and expects to be back in touch with you later today on the path forward. Feel free to call or send email if there are still outstanding issues after you hear from Linda. Thanks,

John Leahy

From: Bill Stringfellow Quest [<mailto:bill@questproducts.us>]
Sent: Monday, March 17, 2014 4:36 PM
To: Hollis, Linda; Leahy, John
Cc: Bryceland, Andrew; Cole, Leonard S.; McNally, Robert
Subject: Reliant Systemic Fungicide EPA.No 83416-1 submission
Importance: High

Ms. Hollis:

Thank you for discussing over the telephone last Friday our application to amend EPA Reg. No. 83416-1. As outlined below, we request BPPD to approve our pending application to amend our end use ("EP") product that we intend to produce using an integrated system. We believe all of the necessary reviews have been completed by BPPD. We respectfully submit that submitting a new application at this juncture to register a manufacturing use product ("MUP") for incorporation into our EP is neither necessary, cost-effective or consistent with our business plans. As you are aware, we are under significant continuing pressure from the end user community to supply our Reliant Systemic Fungicide product this spring.

Quest Products explained to BPPD in writing from the outset our registration intentions – specifically, to amend our existing registration to permit the production of our EP from an integrated process, as expressly permitted by 40 C.F.R. § 158.325(b). Our original submission cover letter dated Sept. 11, 2013 clearly set forth how and who assisted in its development from BPPD. We requested that BPPD expedite and complete its review of the chemistry section of our application by March 15, 2014 because we are without source of supply, and because we are facing demands from growers for a product that will aid in preventing the loss of trees from disease this spring.

BPPD has completed the front end primary screen of our application package. It completed its technical review, chemistry review and data matrix review as of February 4, 2014, subject to our making some minor additions and correction, which we have addressed or are in process of sending to the reviewer. In summary, BPPD has completed all of the elements for a PRIA code B-681, and we request that, subject to our submitting the last piece of information, BPPD approve our registration. We have completed all of the product chemistry requirements to enable BPPD to approve an EPA produced from an integrated system. 40 C.F.R. § 158.325(b). Moreover, OPP policy clearly permits its divisions to amend an EPA registration from a repack to an integrated process.

While we would hope that you would agree that we have complied with the letter of EPA's regulations, if necessary, we are pleased to confirm our original meeting date of Thursday March 20th at 11:00 a.m. as previously arranged by Andrew Bryceland with you, members of your team and Assistant Director John Leahy. The purpose of this meeting would be to understand from BPPD and OPP why our application is deficient in the context of § 158.325(b) so we, in turn, can explain to growers/end users why we are unable to meet their demands this spring for our product which is intended to prevent the loss of trees from disease.

Thank you for your assistance in this matter. I would appreciate your e-mailing me tomorrow to advise me if it will be necessary for me to travel to Washington to meet with you or Thursday or whether this matter can be resolved without a meeting.

Sincerely,

William Stringfellow

Mono- and di- potassium salts of phosphorous acid
PC Codes: 076416

DP Number(s): 416738
EPA Reg. or File Symbol No: 83416-1



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION/OFFICE OF PESTICIDE PROGRAMS

MEMORANDUM

DATE: March 18, 2014

SUBJECT: Science Review in support of registration amendment for registered product, Reliant Systemic Fungicide, containing 45.8 % w/w Mono-and di- potassium salts of phosphorous acid as active ingredient.

Decision Number:	483282
DP Number:	416738
EPA File Symbol Number:	83416-1
Chemical Class:	Biochemical
PC Code:	076416
CAS Number:	13492-26-7 / 13977-65-6
Active Ingredients:	Mono- and di- potassium salts of phosphorous acid
Tolerance Exemptions:	40 CFR 180.1200
MRID Numbers:	492168-01 and 492168-02

FROM: Clara Fuentes, Ph.D.
Entomologist
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

TO: Gina Burnett, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

ACTION REQUESTED

Quest Products LLC., is requesting to amend its 100 % repack registration of Reliant Systemic Fungicide (EPA Reg. No. 83416-1) to add an unregistered source of active ingredient. The proposed amendment will allow the company to manufacture the product instead of repackaging an EPA registered source. In support of this action, the registrant has submitted product chemistry data in 492168-01 and 492168-02, and is citing data with offer to pay from MRIDs 448735-01 to -06 to satisfy acute mammalian toxicity data requirements. The registrant is providing rationale and citing studies from MRIDs 467082-19; 481934-03; 484985-13; 466458-02; 477608-31; 477608-32; 477608-33; 477608-34, and 477608-37 to satisfy subchronic mammalian toxicity data requirements. Cited data from MRIDs 44875-08 to -11; 481376-01 and 477608-27 is submitted in fulfillment of non-target organisms' data requirement. In addition, this submission includes amended copies of product label adding new applications to agricultural and residential uses, and signed copies of Pre-reaction and Post-reaction CSFs, for Alternate formulation, dated 8-30-13, and for Basic formulation, dated 3-9-12, and most recent copies of updated CSFs, dated 3-14-2014.

RECOMMENDATIONS AND CONCLUSIONS

1. Product chemistry: Unacceptable.

1a. Deficiency: The registrant needs to satisfy the requirement for Corrosion Characteristics data. These data are required for manufacturing and end-use product according to 40 CFR §158.2010.

1b. Deficiency: The registrant needs to include MSDSs from the suppliers of active and inert ingredients, [REDACTED]

[REDACTED] listed on the CSFs for Post-reaction Alternative and basic formulations, dated 8-30-2013, and 3-14-2014, respectively.

1c. Deficiency: The submitted MSDSs are from [REDACTED] do not correspond with suppliers of active and inert ingredients listed on either, the CSFs dated 8-30-2014 for Alternative formulation, nor the most recent CSF dated 3-14-1, for Basic formulation. The suppliers listed on Post-reaction Alternative formulation CSF (Dated 8-30-13) and Post-reaction Basic formulation CSF, dated 3-14-14, are [REDACTED]

1d. Deficiency: [REDACTED] are listed as suppliers of active ingredients listed on Pre-reaction CSF, dated 8-30-2013, for

Alternative formulation of end-use product, Reliant Systemic Fungicide. In MRID (pg. 11) however, these active ingredients are described as materials used to produce the product.

1e. Deficiency: Pre-reaction and Post-reaction CSFs do not seem to correspond in composition, but the registrant makes no distinction between them, because the product name on item 3, and values listed for density and pH in items 7 and 8, respectively, on both CSFs are the same. The registrant should verify the identity of each CSF, and that Density and pH values listed on items 7 and 8, respectively, of these different CSFs are identical for both Pre-reaction and Post-reaction Alternative formulation.

2. Mammalian Toxicity: Acceptable.

The registrant has cited studies in MRIDs 448735-01 to 448735-06 in fulfillment of acute mammalian toxicity data requirement. The product is classified in toxicity category III for dermal toxicity and eye irritation. The registrant has provided rationale together with cited studies in MRIDs 467082-19; 477608-31; 481934-03; 484985-13; 466458-02; 477608-32; 466458-03; 477608-33; 477608-34, and 477608-37 to satisfy each individual Subchronic mammalian toxicity data requirement.

3. Non-Target Organisms: Acceptable.

The registrant has adequately satisfied the required non-target organisms' studies, oral and dietary avian toxicity, toxicity of fresh water invertebrate and fresh water fish, non-target plants, and non-target insects with cited data in MRIDs 448735-08 to 448735-11; 481376-01 and 477608-27.

BACKGROUND INFORMATION

Reliant Systemic Fungicide (EPA Reg. No. 83416-1) is a Systemic fungicide for the control of various plant diseases affecting fruits and vegetables. The current registration is a 100 % repack of Mono- and di- potassium salts of phosphorous acid [REDACTED]. The registrant is requesting a change in registration to add an unregistered source of active ingredient. In addition, the registrant is proposing to expand applications range for agricultural and residential uses to include control of various plant pathogens affecting fruits and vegetable plants, herbs and spices, and in hydroponic plant production.

STUDY SUMMARY

Product Chemistry:

Product ingredient source information may be entitled to confidential treatment

TABLE 1. Physical and Chemical Properties for Reliant Systemic Fungicide		
Guideline Reference No./Property	Description of Result	Methods
830.6302 Color	Clear blue	Visual inspection
830.6303 Physical State	Liquid	Visual inspection
830.6304 Odor	Odorless	Qualitative determination
830.6313 Stability	N/A	
830.6315 Flammability	N/A	
830.6316 Explodability	N/A	
830.6317 Storage Stability	Data to be submitted upon completion of study	
830.6319 Miscibility	N/A	
830.6320 Corrosion Characteristics	REQUIRED	
830.7000 pH	5.72 at 22 °C	pH meter
830.7050 UV/Visible Absorption	N/A	
830.7100 Viscosity	3.17 nm ² at 24 °C 2.52 nm ² at 43 °C	Gravitational flow thru capillary viscometer
830.7200 Melting Range	N/A	
830.7220 Boiling Range	107.2 °C	Calculated $\Delta T_b = K_b m i$
830.7300 Density/Relative Density/Bulk Density	1.37 g/ml	Calculated: D = mass (g) / vol. (ml) Pycnometer
830.7520 Particle size, fiber length, diameter distribution	N/A	
830.7550 Partition coefficient (n-Octanol/water)	N/A	
830.7840 Water Solubility	N/A	
830.7950 Vapor Pressure	N/A	

Data from MRID 492168-02.

Toxicity

<u>Study Type/OPPTS Guideline</u>	<u>LD₅₀/LC₅₀/Results</u>	<u>Toxicity Category</u>	<u>MRID</u>
Acute Oral Toxicity/OPPTS 870.1100	> 5,000 mg/kg	IV	448735-01
Acute Dermal Toxicity/OPPTS 870.1200	> 2,000 mg/kg	III	448735-02
Acute Inhalation Toxicity/OPPTS 870.1300	> 4.4 mg/L	IV	448735-05
Acute Eye Irritation/OPPTS 870.2400	Ocular irritation cleared within 72 hrs.	III	448735-04
Acute Dermal Irritation/OPPTS 870.2500	Not a dermal irritant	IV	448735-03
Skin Sensitization/OPPTS 870.2600	Not a sensitizer	IV	448735-06

Test substance was 53 % Mono and Di-potassium phosphite.

The Required sub-chronic mammalian toxicity data are cited from the following MRIDs: 467082-19; 477608-31; 481934-03; 484985-13; 466458-02; 477608-32; 466458-03; 477608-33; 477608-34, and 477608-37. The registrant offers the following rationale to address each data requirement individually:

90-days Oral toxicity (OCSPP 870.3100):

An exemption from the requirement of a tolerance is established in 40 CFR 180.1200 for residues of phosphorous acid and its ammonium, sodium and potassium salts in or on all food commodities when used as an agricultural fungicide on food crops.

90-days dermal (OCSPP 870.3250): No purposeful application to the human skin which would result in prolonged dermal exposure to the product is expected.

90-days Inhalation (OCSPP 870. 3465): There is little likelihood of significant levels of repeated inhalation exposure to the product as gas, vapor or aerosol spray.

Prenatal Development (OCSPP 870.3700): Under common practice and product use pattern, significant product exposure to human females is unlikely.

Mutagenicity (OCSPP 870.7200): Neither the active ingredient nor its metabolites are related to a known mutagen nor they belong to any chemical class containing a known mutagen.

Non-Target Organisms:

<u>Study Type/OPPTS Guideline</u>	<u>LD₅₀/LC₅₀/Results</u>	<u>Toxicity Category</u>	<u>MRID</u>
Avian Acute Oral/OPPTS 850.2100	> 2,000 mg/kg	Slightly toxic	448735-08
Avian Dietary/OPPTS 850.2200	> 5,000 ppm	IV	448735-09
Freshwater Invertebrate/OPPTS 850.1010	> 1,200 mg/L	Practically non-toxic	448735-11
Freshwater Fish LC50/OPPTS 850.1075	> 790 mg/L	IV	448735-10
Non-target Plants/OPPTS 850.4100	No phytotoxic		481376-01
Non-target Insects 850.3020	No toxic to bees		477608-27

Test substance was 53 % Mono- and di-potassium phosphite, 12.2 % phosphorus, 28 % phosphorous.

cc: Clara Fuentes, RAL Gina Burnett, BPPD Chron File, IHAD/ARS FT, PY-S: 03/18/2014.

CONFIDENTIAL APPENDIX

Pages 28-30 Manufacturing process information may be entitled to confidential treatment

WAIVER MATRIX

Date September 16, 2013

EPA Reg. No. 83416-1

Registrant's Name & Address:

Quest Products LLC, 11712 230th St., Linwood, KS 66052

Product

RELIANT SYSTEMIC FUNGICIDE

Ingredient Mono- and di- potassium salts of phosphorous acid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Rationale* (See table below)
870-3100	90-day oral (one species)			
870-3250	90-day dermal rat			
870-3465	90-day inhalation rat			
870-3700	Prenatal developmental - rat			
830-7200	Bacterial reverse mutation test			
870-5300/5375	<i>In vitro</i> mammalian cell assay			
870-5385/5895	<i>In vivo</i> Mammalian Cytogenetics			

* Waiver rationale for each guideline requirement is not limited to what is stated or reflect the reasoning made to request and secure each waiver.



11712 230th St.
Linwood, KS 66052

March 13, 2014

Leonard S. Cole, Jr., Senior Regulatory Specialist
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division (7511P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

RE: RELIANT SYSTEMIC FUNGICIDE, EPA Reg. No. 83416-1
Submission of requested documents

Quest Products LLC., 11712 230th Street, Linwood, KS 66052, is submitting the following information to address several deficiencies in our submitted amendment of 9-11-13:

- Corrected Pre Reaction Confidential Statement of Formula to fix CAS# for [REDACTED]
- Corrected Post Reaction Confidential Statement of Formula to fix nomenclature and CAS# for [REDACTED] impurity;
- Revised Data Matrix that includes MRID numbers for submitted Product Chemistry, additions of uv/visible and water solubility submissions and, addition of citations for 850-3020 and 850-4100 guideline requirements;
- Public copy of Data Matrix and;
- Material Safety Data Sheets for Phosphorous Acid and Potassium Hydroxide (Pre Reaction materials). Additionally, an MSDS for the [REDACTED] used as a Post Reaction material is attached.

Please be advised that Quest will submit studies regarding Storage Stability (830-6317) and Corrosion Characterization (830-6320) as indicated in our submission.

If you have any questions or need any additional information, please to contact me at (215) 715 6419 or <mailto:rrosenwasser@verizon.net>.

Sincerely,

Robert Rosenwasser
Agent for Quest Products, LLC

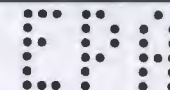


Inert ingredient information may be entitled to confidential treatment

Manufacturing process information may be entitled to confidential treatment



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DATA MATRIX

Date September 16, 2013	EPA Reg. No./File Symbol 83416-1	Page 1 of 3
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Applicant's/Registrant's Name & Address: Quest Products LLC, 11712 230 th St., Linwood, KS 66052	Product RELIANT SYSTEMIC FUNGICIDE
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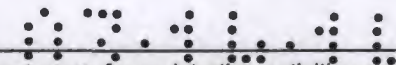
Ingredient Mono- and di- potassium salts of phosphorous acid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830-1550	Product identification and composition	49216801	Quest Products LLC	Own	
830-1600	Description of materials used to produce product	49216801	Quest Products LLC	Own	
830-1620	Beginning materials and Mfg. process	49216801	Quest Products LLC	Own	
830-1650	Description of Formulation Process	49216801	Quest Products LLC	Own	
830-1670	Formation of Impurities	49216801	Quest Products LLC	Own	
830.1700	Preliminary analysis	49216801	Quest Products LLC	Own	
830-1750	Certified limits	49216801	Quest Products LLC	Own	
830-1800	Enforcement analytical method	49216801	Quest Products LLC	Own	
830-6302	Color	49216802	Quest Products LLC	Own	
830-6303	Physical state	49216802	Quest Products LLC	Own	
830.6304	Odor	49216802	Quest Products LLC	Own	
830-6314	Oxidizing or reducing action	49216802	Quest Products LLC	Own	
830-6315	Flammability	waiver	Product does not contain any combustible liquids.		
830-6317	Storage stability	49216802	Quest Products LLC	Own	
830-6319	Miscibility	waiver	Product is not an emulsifiable liquid and is not to be diluted with petroleum solvents.		
830-6320	Corrosion characterization	49216802	Quest Products LLC	Own	



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Form Approved OMB No. 2070-0060



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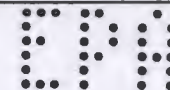
Date September 16, 2013	EPA Reg. No./File Symbol 83416-1	Page 2 of 3
Applicant's/Registrant's Name & Address: Quest Products LLC, 11712 230 th St., Linwood, KS 66052	Product RELIANT SYSTEMIC FUNGICIDE	

Ingredient Mono- and di- potassium salts of phosphorous acid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830-7000	pH	49216802	Quest Products LLC	Own	
830-7050	UV/Visible	Submitted	Quest Products LLC	Own	
830-7100	Viscosity	49216802	Quest Products LLC	Own	
830-7220	Boiling point/range	49216802	Quest Products LLC	Own	
830-7300	Density	49216802	Quest Products LLC	Own	
830-7840	Water solubility	Submitted	Quest Products LLC	Own	
830-7950	Vapor pressure	waiver	Not required for salts		
850-1010	Invertebrate acute toxicity, freshwater	44873511	JH Biotech	Offer to pay	
850-1075	Freshwater acute toxicity	44873510	JH Biotech	Offer to pay	
850-2100	Avian acute oral toxicity	44873508	JH Biotech	Offer to pay	
850-2200	Avian dietary toxicity	44873509	JH Biotech	Offer to pay	
850-3020	Honeybee acute contact toxicity	47760827	Plant Protectants, LLC	Offer to pay	
850-4100	Seedling emergence and growth	48137601	Plant Protectants, LLC	Offer to pay	
870-1100	Acute toxicity – Oral	44873501	JH Biotech	Offer to pay	



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Applicant's/Registrant's Name & Address: Quest Products LLC, 11712 230 th St., Linwood, KS 66052	Product RELIANT SYSTEMIC FUNGICIDE	

Ingredient Mono- and di- potassium salts of phosphorous acid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870-1200	Acute toxicity – Dermal	44873502	JH Biotech	Offer to pay	
870-1300	Acute toxicity – Inhalation	44873505	JH Biotech	Offer to pay	
870-2400	Primary Eye Irritation	44873504	JH Biotech	Offer to pay	
870-1300	Acute toxicity – Inhalation	44873505	JH Biotech	Offer to pay	
870-2400	Primary Eye Irritation	44873504	JH Biotech	Offer to pay	
870-2500	Primary Dermal Irritation	44873503	JH Biotech	Offer to pay	
870-2600	Dermal sensitization	44873506	JH Biotech	Offer to pay	
870-3100	90-day oral (one species)		Quest Products LLC	Waiver	
870-3250	90-day dermal rat		Quest Products LLC	Waiver	
870-3465	90-day inhalation rat		Quest Products LLC	Waiver	
870-3700	Prenatal developmental - rat		Quest Products LLC	Waiver	
870-5100	Bacterial reverse mutation test		Quest Products LLC	Waiver	
870-5300/5375	In vitro mammalian cell assay		Quest Products LLC	Waiver	
870-5385/5895	In vivo Mammalian Cytogenetics		Quest Products LLC	Waiver	

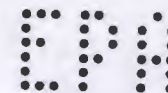
Signature 	Name and Title Robert Rosenwasser Agent, Quest Products LLC.	Date March 14, 2014
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WAIVER MATRIX					EPH
Date September 16, 2013			EPA Reg. No. 83416-1		
Registrant's Name & Address: Quest Products LLC, 11712 230 th St., Linwood, KS 66052			Product RELIANT SYSTEMIC FUNGICIDE		
Ingredient Mono- and di- potassium salts of phosphorous acid					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Rationale* (See note below)	
870-3100	90-day oral (one species)	46708219 47760831 48193403 48498513	Actagro, Plant Protectants Winfield Luxembourg-Pamol	Waiver-An exemption from the requirement of a tolerance is established for residues of phosphorous acid and its ammonium, sodium and potassium salts in or on all food commodities when used as an agricultural fungicide on food crops. (40 CFR 180.1200)	
870-3250	90-day dermal rat	46645802 46708219 47760832 48193403	Biagro Western Sales Actagro Plant Protectants Winfield	Waiver-No purposeful application to the human skin or which would result in comparable prolonged human exposure to the product.	
870-3465	90-day inhalation rat	46645803 46708219 47760833 48193403	Biagro Western Sales Actagro Plant Protectants Winfield	Waiver-There is little likelihood of significant levels of repeated inhalation exposure to the pesticide as a gas, vapor, or aerosol.	
870-3700	Prenatal developmental - rat	47760834 48193403 48498513	Plant Protectants Winfield Luxembourg-Pamol	Waiver-Product under widespread and commonly recognized practice may not reasonably be expected to result in significant exposure to female humans (e.g., occupational exposure).	
830-7200	Bacterial reverse mutation test	47760837 48193403	Plant Protectants Winfield	Waiver	
870-5300/5375	In vitro mammalian cell assay	47760837 48193403 48498513	Plant Protectants Winfield Luxembourg-Pamol	Waiver-The active ingredient (or its metabolites) is not structurally related to a known mutagen or belongs to any chemical class of compounds containing a known mutagen.	
870-5385/5895	In vivo Mammalian Cytogenetics	48498513	Luxembourg-Pamol	Waiver	

* Waiver rationale for each guideline requirement is not limited to what is stated or reflect the reasoning made to request and secure each waiver.



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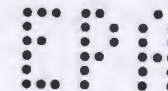
Date September 16, 2013	EPA Reg. No./File Symbol 83416-1	Page 1 of 3
Applicant's/Registrant's Name & Address: Quest Products LLC, 11712 230 th St., Linwood, KS 66052	Product RELIANT SYSTEMIC FUNGICIDE	

Ingredient Mono- and di- potassium salts of phosphorous acid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830-1550	Product identification and composition				
830-1600	Description of materials used to produce product				
830-1620	Beginning materials and Mfg. process				
830-1650	Description of Formulation Process				
830-1670	Formation of Impurities				
830.1700	Preliminary analysis				
830-1750	Certified limits				
830-1800	Enforcement analytical method				
830-6302	Color				
830-6303	Physical state				
830.6304	Odor				
830-6314	Oxidizing or reducing action				
830-6315	Flammability				
830-6317	Storage stability				
830-6319	Miscibility				
830-6320	Corrosion characterization				



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DATA MATRIX

Date September 16, 2013

EPA Reg. No./File Symbol 83416-1

Page 3 of 3

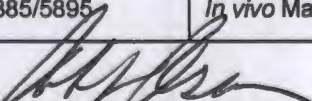
Applicant's/Registrant's Name & Address:

Quest Products LLC, 11712 230th St., Linwood, KS 66052

Product

RELIANT SYSTEMIC FUNGICIDE

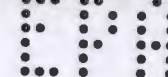
Ingredient Mono- and di- potassium salts of phosphorous acid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870-1200	Acute toxicity – Dermal				
870-1300	Acute toxicity – Inhalation				
870-2400	Primary Eye Irritation				
870-1300	Acute toxicity – Inhalation				
870-2400	Primary Eye Irritation				
870-2500	Primary Dermal Irritation				
870-2600	Dermal sensitization				
870-3100	90-day oral (one species)				
870-3250	90-day dermal rat				
870-3465	90-day inhalation rat				
870-3700	Prenatal developmental - rat				
870-5100	Bacterial reverse mutation test				
870-5300/5375	<i>In vitro</i> mammalian cell assay				
870-5385/5895	<i>In vivo</i> Mammalian Cytogenetics				
Signature 		Name and Title Robert Rosenwasser Agent, Quest Products LLC.		Date March 14, 2014	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060



Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director: OPPE Information Management Division (2137) U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date September 16, 2013

EPA Reg. No./File Symbol 83416-1

Page 2 of 3

Applicant's/Registrant's Name & Address:

Quest Products LLC, 11712 230th St., Linwood, KS 66052

Product

RELIANT SYSTEMIC FUNGICIDE

Ingredient Mono- and di- potassium salts of phosphorous acid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830-7000	pH				
830-7050	UV/Visible				
830-7100	Viscosity				
830-7220	Boiling point/range				
830-7300	Density				
830-7840	Water solubility				
830-7950	Vapor pressure				
850-1010	Invertebrate acute toxicity, freshwater				
850-1075	Freshwater acute toxicity				
850-2100	Avian acute oral toxicity				
850-2200	Avian dietary toxicity				
850-3020	Honeybee acute contact toxicity				
850-4100	Seedling emergence and growth				
870-1100	Acute toxicity -- Oral				



11712 230 Street
Linwood, Kansas 66052
Phone 785-542-2577
Fax 785-542-2531

March 12, 2014

Dear Linda Hollis:

Yes, we want to proceed with a face-to-face meeting as soon as possible with you, Andrew Bryceland and Leonard Cole regarding the Reliant Systemic Fungicide EPA No 83416-1 submission. Preferably the meeting could take place next week on March 20th or 21st.

This request is also being sent to you via paper document overnight to assure that you are in receipt of it. This because telephonic requests and email communications have not been effective methods of communicating with you or your direct report team members because they go unanswered.

Robert Rosenwasser of R&R Consulting, our regulatory representative, has just now remarkably been able to communicate with Leonard Cole about the status of the submission and addressing identified deficiencies that we have been requesting communications on since the date of submission. These requests for status and progress updates were repeatedly requested specifically in case if additions or modifications were needed to the original package, submitted on September 11, 2013, because we are without supply for the season. This was communicated in the original document submission.

Recently identified deficiencies by Mr. Cole as of today will be addressed and submitted by R&R Consulting on Quest's behalf on or before the face-to-face meeting with you and your team members.

If any communication of substance would have taken place previously with you or your department team as we repeatedly requested we would not be in this current situation of having growers/end users calling and writing EPA for action and requesting a face to face meeting.

In regards to the 100% Repack Guidance Document used for reference in this submittal, this document and the guidance provided for the submittal itself was provided by Gina Burnett, I believe one of your team members.

This was clearly presented and communicated in the original submission as to how the submittal was originally developed and from where the guidance was derived.

As to Leonard Cole being unavailable during January and February, I am dumbfounded that EPA backup staff was not available or able to address his area of responsibility while unavailable for such a prolonged period of time.

In reference to the face-to-face meeting agenda our talking points are still unchanged from previous communication:

What is the current status of the chemistry review?

If the chemistry review is finalized and approved can a letter of approval for the new source of active ingredient be issued so that we can produce product for the current seasonal demand?

This has always been the basis for our request for an accelerated review of the chemistry side of the submission.

The additional uses submitted can then be reviewed as per the PRIA date or can they be approved as well at this time? The chemistry submission section is the most important of the entire submission.

Regards,


William Stringfellow

cc: Robert McNally
Robert Rosenwasser
Leonard Cole
Andrew Bryceland

9355
5555

OPPTS 830.6314 Oxidation/Reduction: Chemical Incompatibility

Information on the oxidation and reduction potential of Reliant Systemic Fungicide was obtained through a knowledge of its chemistry by a PhD chemist familiar with the product and methods of its application. This narrative is as follows:

Reliant Systemic Fungicide (mono- and di- potassium salts of phosphorous acid) contains a phosphorus atom in its lowest oxidation state of +3. As such, mono- and di- potassium salts of phosphorous acid are readily oxidized by oxidizing agents such as halogen, peroxygen compounds and heavy metal ions. Upon oxidation, mono- and di- potassium salts of phosphorous acid reduce dissolved molecular iodine to iodide ion, a reaction which forms that basis for its analytical determination. Direct contact of the product with oxidizing agents is exothermic and should be avoided.

Since mono- and di- potassium salts of phosphorous acid are in the reduced +3 oxidation state they resist further reduction by common reducing agents such as bisulfite, metabisulfite thiosulfate and nitrite salts. Mono- and di- potassium salts of phosphorous acid are also unreactive to the strong reducing reagent hydrogen sulfide (H_2S).

Only stainless steel and plastic materials such as high-density polyethylene, polypropylene, polytetrafluoroethylene, polyvinylidene fluoride, polyvinylchloride are suitable for piping and pumping solutions of mono- and di- potassium salts of phosphorous acid. Nylon is slowly attacked by mono- and di- potassium salts of phosphorous acid and is not recommended for long-term use.

Mono- and di- potassium salts of phosphorous acid should be packaged in containers constructed of high-density polyethylene only.

OPPTS 830.6315 Flammability

The product is not a combustible liquid. As such, this study is not applicable.

OPPTS 830.6316 Explodability

The product has no constituents with chemical bonds or functional groups associated with explodable chemicals. As such, this study is not applicable.

OPPTS 830.6317 Storage Stability and OPPTS 830.6320 Corrosion Characteristics

A sample of Reliant Systemic Fungicide from Lot 071013 was employed in this study. The sample was initially analyzed in duplicate using the Enforcement Analytical Method, and stored in a non-climate controlled warehouse. At each test interval, (1, 3, 6, 9 and 12

month periods) the Reliant Systemic Fungicide solutions will be removed for analysis in duplicate using the Enforcement Analytical Method. The arithmetic mean of the initial results, expressed as % m/V active ingredient in Reliant Systemic Fungicide is given in Table I. The % loss of active ingredients at each test interval is calculated using the equation:

$$\% \text{ Loss of Active Ingredient (a.i.)} = \frac{\text{Conc. a.i. (t = 0)} - \text{Conc. a.i. (t = t)} \times 100}{\text{Conc. a.i. (t = 0)}}$$

Table I

Date (Test interval)	Warehouse Temperature /°F	% AI	% Loss in AI
8/26/13 (Initial analysis)	72	45.81	N/A
1 month			
3 month			
6 month			
9 month			
12 month			

N/A = Not applicable

The observations made during the examination of the sample for physical changes in the sample, sample container, and its closure is documented in Table II.

Table II

Date (Test interval)	Note condition of sample	Note condition of container and its closure
8/26/13 (Initial analysis)	Single phase, blue liquid	Both are brand new

The results of this study are to be submitted to EPA in advance of completing the full one-year storage stability study requirement. Therefore, this interim report represents the storage stability data obtained at the initial test interval for a conditional registration request pending compliance with all the requirements when the one-year study is complete.

A final report will be generated that documents the measurements and observations concerning changes in the physical state of the product or the product container at each test interval. The report will include the results of the quantitative analyses for the active ingredient and the m/V % of active ingredient remaining will be calculated. A statistical evaluation of the precision and accuracy of the measurements will be included.

OPPTS 830.6319 Miscibility

The product is not an emulsifiable liquid intended to be diluted with petroleum solvents. As such, this study is not applicable.

OPPTS 830.6321 Dielectric breakdown voltage

Not required for a manufacturing-use product.

OPPTS 830.7000 pH

The pH of Reliant Systemic Fungicide from lot number 071013 was measured. Prior to making the measurement, a glass electrode (Hanna Instruments HI 1131) used in conjunction with a pH meter (Hanna Instruments pH 2210 Microprocessor pH Meter) was calibrated with a 2-point calibration using NIST buffer solutions of pH 7.00 and 4.01. The average of duplicate pH measurements at 22 °C was 5.72.

OPPTS 830.7050 UV/Visible Absorption

Not required for a manufacturing-use product.

OPPTS 830.7100 Viscosity

Kinematic viscosity data on Reliant Systemic Fungicide solution from lot number 071013 was obtained using a method based on its gravitational flow through a capillary.

A calibrated Ubbelohde glass capillary viscometer (Universal size No.1B) conforming to ASTM D 445, ASTM D 446, ISO 3104 and ISO 3105 standards was used for the measurements. The determinations were made at a temperature of 24 °C and at 43 °C.

Receipt for Section 3

S: 948530 Milestone Email:

Regulatory Type: Product Registration - Section 3 Resubmission: ☐ Yes ☒ No

Application Type: Miscellaneous Receipt Fee For Service: ☐ Yes ☒ No

Company: 83416 QUEST PRODUCTS L.L.C. ☒ Billable: ☐ Yes ☒ No

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91

Product #: **83416-1** Product Name: RELIANT SYSTEMIC FUNGICIDE

Override#

Me Too Section3: Me Too Product Name:

Application Date: 21-Feb-2014 OPP Rec'd Date: 05-Mar-2014

Front End Date: 05-Mar-2014 Risk Manager Send Date: 05-Mar-2014

FFS Due Date: Negotiated Due Date:

OPP Target Date:

Fast Track: ☐ New Ingredient: ☐

Receipt Description:

Quest is requesting an accelerated review of the amendment filed 9/16/2013. The purpose of the application is to add an unregistered source of supply of the active ingredient and to review an amended product label

Form A: ☐ Signature Date: Form B: ☐ Signature Date:

Receipt Content

Other Accelerated review of

12:20 PM 3/18/2014

Gina



11712 230th Street
Linwood, Kansas 66052
785-542-2577

February 21, 2014

Linda Hollis, Branch Chief
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division (7511P)
U.S. Environmental Protection Agency
One Potomac Yard (South Building)
2777 S. Crystal Drive
Arlington, VA 22202

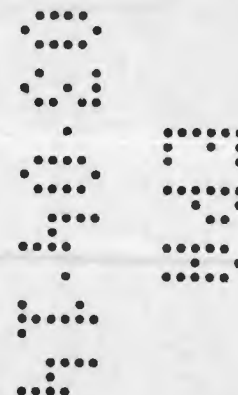
**RE: Reliant Systemic Fungicide, EPA Reg. No. 83416-1
Accelerated Review of Amendment, PRIA Code B681**

Quest Products, LLC., 11712 230th Street, Linwood, Kansas 66052 is requesting an accelerated review of our amendment filed on September 16, 2013. The purpose of the application was to add an unregistered source of supply of the active ingredient, Mono- and di- potassium salts of phosphorous acid, to the registration, and to review an amended product label.

Currently, Reliant Systemic Fungicide has no available source of supply and is unable to produce product for its customers. Quest Products has petitioned the Agency to revamp its current repack registration to allow for the production of its own source of active ingredient. However, the timing to achieve the approval of the amendment to enable Quest to restart production will not meet the demand made by our customers who treat Sudden Oak Death, *Phytophthora ramorum* (determined to be an invasive species by APHIS) in California and other States.

Reliant Systemic Fungicide has been proven to be an effective product to prevent the spread of this disease pathogen from infecting and killing historic trees in the California and other States. Trees left untreated can result in potentially hazardous public safety concerns, reduction in property values, aesthetic loss and further spread of the disease. Attached are three testimonials from several hundred current Reliant /Quest customers who are extremely concerned about the potential lack of product as they approach March 15, target to treat trees.

In order for these companies to obtain the product they need to treat Sudden Oak Death, Quest Products needs to gain EPA approval of its amendment, now 5 months in review.



Without the availability of Reliant Systemic Fungicide, Quest Products is concerned over the potential use of conventional pesticides by its customers that do not have the expertise, efficacy or safety profile of our biopesticide.

In order to obtain an accelerated result, Quest Products is requesting the Agency to forgo the requested review of the amended label and finalize the action once the Product Chemistry is reviewed and approved. Obtaining permission to manufacture the active ingredient is key to manufacturing the product and distributing it to our customers in time to make these critical treatments.

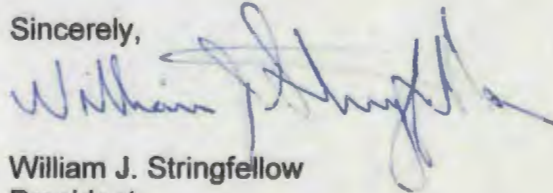
Quest Products respectfully requests that the Agency allow this review to conclude when the Product Chemistry is completed and any other administrative actions are completed, such as review of the Data Matrix.

With the potential to gain approval of this amendment as soon as possible, Quest Products would be able to produce and distribute product to our customers and hopefully meet their treatment needs in mid-March.

Please review this request with your utmost deliberation and let us know as soon as possible what the Agency can and will do to assist in this endeavor.

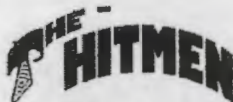
If you have any questions, please feel free to call me at 785-542-2577 or send an email to bill@questproducts.us.

Sincerely,



William J. Stringfellow
President
Quest Products, LLC

CC: Leonard S. Cole, Jr., Senior Regulatory Specialist
Andrew Bryceland, Team Leader



TERMITE & PEST
CONTROL, INC.

"Targeting Quality Since 1978"



February 13, 2014

Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

RE: Accelerated Review of Reliant Systemic Fungicide

To whom it may concern,

The Hitmen Termite & Pest Control is a company that is involved with the care and treatment of many Heritage or Signature Oak trees in landscapes, parks and right of ways throughout California. These trees are under attack by the invasive pathogen known as Sudden Oak Death, *Phytophthora ramorum*.

Many property owners have requested we treat these trees by March 15 to prevent the loss of these valuable trees. Left untreated this could cause hazardous tree situations, potential public safety, reduction in property values, aesthetic loss, and further spread of the SOD pathogen.

We are extremely limited as to products that are approved and have been proven to control or suppress this invasive fatal tree killing disease. Reliant Systemic Fungicide has previously demonstrated excellent control of this pathogen and is our product and application method of choice.

We urge EPA to accelerate the review of the Reliant Systemic Fungicide product so that we may use the product in our early spring management programs for tree health.

Regards,

Mike English

Sonoma County
(707) 526-6055

Solano County
(707) 427-3000

Napa County
(707) 963-1713

Marin County
(415) 456-6777

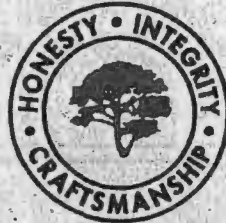
East Bay
(510) 452-9536

TOLL FREE
(800) 351-2488

Main Office 600 E. Todd Road, Santa Rosa, CA 95407
Solano/East Bay Office 229 Benton Court, Suisun City, CA 94585
LIC. # PR1342 Bonded and Insured

TREEMASTERS

3175 Kerner Blvd Ste. A
San Rafael, CA 94901
(415) 455-9933 Main
(415) 455-9934 Fax



WWW.TREEMASTERS.COM
Email: treemail@treemasters.com



2/12/14

To Whom It May Concern at U.S. EPA

Reference: Accelerated Review of Reliant Systemic Fungicide

TREEMASTERS is a Bay Area California tree service that is involved with the care and treatment of many Heritage or Signature Oak trees in landscapes, parks and right of ways that are under attack by the invasive pathogen known as Sudden Oak Death, *Phytophthora ramorum*.

Many property owners have requested we treat these trees by March 15th to prevent the loss of these valuable trees to stop the further spread of the SOD pathogen. Without treatment, removal of these trees may cause the reduction of property values and aesthetic loss, which is detrimental to the owners' properties. Benefits of removal alone without treatment may reduce hazardous tree situations and potential public safety.

We are extremely limited to products that have been approved by EPA and are proven to control or suppress this invasive fatal tree killing disease. Reliant Systemic Fungicide has previously demonstrated excellent control of this pathogen and is our product and application method of choice.

We urge EPA to accelerate the review of the Reliant Systemic Fungicide product so that we may use the product in our early spring management programs for tree health.

Respectfully,

Tad Jacobs
Owner
TREEMASTERS

"Providing great care and attention
to the ONE TREE we are working on at that moment."



James M. McClenahan
John H. McClenahan
Joshua T. McClenahan



Gary F. Armstrong
Miguel A. Berumen
Juan Larios

Contractors Lic. #651341
1 Arastradero Road, Portola Valley, CA 94028-8012
Telephone (650) 326-8781
Fax (650) 854-1267
www.spmcclenahan.com

February 5, 2014

To Whom It May Concern:

Our companies have been engaged in preserving oak trees in the San Francisco Bay Area for over 100 years. In the last decade an invasive disease classified by APHIS (American Plant Health Inspection Service) as Sudden Oak Death (*Phytophthora ramorum*) has been destroying oak trees in our region. Reliant Systemic Fungicide provides us an environmentally safe and effective choice to prevent this disease from infecting many historic oak trees in our area.

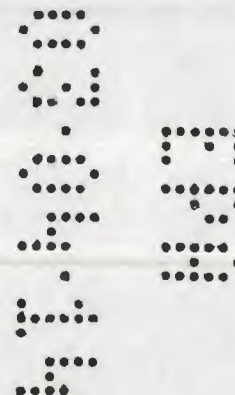
Due to high demand and fear of tree mortality, many tree owners are requesting applications of this product in early March to control and prevent the spread of SOD. An accelerated review of Registration of Reliant would provide applicators and save many of these Heritage Trees as a means to treat thousands of trees in March of this year. In addition, Bill Stringfellow with Quest Products has been very helpful instructing end users on safe and effective use of this compound.

Should you have any questions, or if we may be of further assistance in these concerns, kindly contact our office at any time.

Sincerely,

John H. McClenahan, CEO
ISA Board Certified Master Arborist – 1476B
PNW-ISA CTRA 1186
S. P. McClenahan Co., Inc

JHMc: cm



Mono- and di- potassium salts of phosphorous acid
PC Codes: 076416

DP Number(s): 416738
EPA Reg. or File Symbol No: 83416-1



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION/OFFICE OF PESTICIDE PROGRAMS

MEMORANDUM

DATE: Feb. 4, 2014

SUBJECT: Science Review in support of registration amendment for registered product,
Reliant Systemic Fungicide, containing 45.8 % w/w Mono-and di- potassium salts
of phosphorous acid as active ingredient.

Decision Number:	483282
DP Number:	416738
EPA File Symbol Number:	83416-1
Chemical Class:	Biochemical
PC Code:	076416
CAS Number:	13492-26-7 / 13977-65-6
Active Ingredients:	Mono- and di- potassium salts of phosphorous acid
Tolerance Exemptions:	40 CFR 180.1200
MRID Numbers:	492168-01 and 492168-02

FROM: Clara Fuentes, Ph.D. //
Entomologist
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

TO: Leonard Cole, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

ACTION REQUESTED

Quest Products LLC., is requesting to amend its 100 % repack registration of Reliant Systemic Fungicide (EPA Reg. No. 83416-1) to add an unregistered source of active ingredient. The proposed amendment will allow the company to manufacture the product instead of repackaging an EPA registered source. In support of this action, the registrant has submitted product chemistry data in 492168-01 and 492168-02, it is citing data with offer to pay from acute mammalian toxicity in MRIDs 448735-01 to -06, and non-target organism studies in MRIDs 44875-08 to -11. In addition, the registrant has submitted amended copies of product label adding new applications to agricultural and residential uses, and signed copies of CSFs, for alternate formulation, dated 8-30-13, and for basic formulation, dated 3-9-12.

RECOMMENDATIONS AND CONCLUSIONS

1. Product chemistry: Unacceptable.

1a. Deficiency: The registrant needs to satisfy the following physical/chemical characteristic data requirements: Corrosion Characteristics, UV/Visible Absorption, and Water Solubility. These data requirements are applicable to this product, produced by an integrated formulation system, containing an unregistered source of active ingredient.

1b. Deficiency: The CAS No. [REDACTED] for one of the impurities listed on the CSF is unknown to the Agency (Refer to Confidential Appendix for information on product composition and manufacturing process).

1c. Deficiency: The CAS No. [REDACTED] listed in Pre-Reaction CSF for one of the starting materials is incorrect. It should be replaced with the correct CAS No. [REDACTED] (Refer to Confidential Appendix for information on product composition and manufacturing process).

1d. Deficiency: The registrant needs to include MSDSs from the listed suppliers of active and inert ingredients present in the formulation.

2. Mammalian Toxicity: Acceptable.

Acute mammalian toxicity data from cited studies in MRIDs 448735-01 to 448735-06 are Acceptable. The product is classified in toxicity category III for dermal toxicity and eye irritation. Required sub-chronic mammalian toxicity data are not being referenced for lack of citable data.

3. Non-Target Organisms: Unacceptable.

Manufacturing process information may be entitled to confidential treatment

3a. Deficiency: Non-target plants and non-target insects data are not been addressed, and they should be. The registrant should address non-target plants and non-target insects' toxicity to satisfy all non-target organisms' data requirements.

Cited data for non-targets oral and dietary avian toxicity, toxicity of fresh water invertebrate and fresh water fish in MRIDs 448735-08 to 448735-11, are **Acceptable**.

BACKGROUND INFORMATION

Reliant Systemic Fungicide (EPA Reg. No. 83416-1) is Systemic fungicide for the control of various plant diseases affecting fruits and vegetables. The current registration is a 100 % repack of Mono- and di- potassium salts of phosphorous acid [REDACTED]. The registrant is requesting a change in registration to add an unregistered source of active ingredient. In addition, the registrant is proposing to expand applications range for agricultural and residential uses to include control of various plant pathogens affecting fruits and vegetable plants, herbs and spices, and hydroponic plant production.

STUDY SUMMARY

Product Chemistry:

TABLE 1. Physical and Chemical Properties for Reliant Systemic Fungicide

Guideline Reference No./Property	Description of Result	Methods
830.6302 Color	Clear blue	Visual inspection
830.6303 Physical State	Liquid	Visual inspection
830.6304 Odor	Odorless	Qualitative determination
830.6313 Stability	N/A	
830.6315 Flammability	N/A	
830.6316 Explodability	N/A	
830.6317 Storage Stability	Data to be submitted upon completion of study	
830.6319 Miscibility	N/A	
830.6320 Corrosion Characteristics	REQUIRED	
830.7000 pH	5.72 at 22 °C	pH meter
830.7050 UV/Visible Absorption	REQUIRED	
830.7100 Viscosity	3.17 nm ² at 24 °C 2.52 nm ² at 43 °C	Gravitational flow thru capillary viscometer
830.7200 Melting Range	N/A	
830.7220 Boiling Range	107.2 °C	Calculated $\Delta T_b = K_b m i$
830.7300 Density/Relative Density/Bulk Density	1.37 g/ml	Calculated: $D = \text{mass (g)} / \text{vol. (ml)}$ Pycnometer
830.7520 Particle size, fiber length, diameter distribution	N/A	
830.7550 Partition coefficient (n-Octanol/water)	N/A	
830.7840 Water Solubility	REQUIRED	
830.7950 Vapor Pressure	N/A	

Data from MRID 492168-02.

Toxicity

Study Type/OPPTS Guideline	LD ₅₀ /LC ₅₀ /Results	Toxicity Category	MRID
Acute Oral Toxicity/OPPTS 870.1100	> 5,000 mg/kg	IV	448735-01
		III	448735-02

<u>Study Type/OPPTS Guideline</u>	<u>LD₅₀/LC₅₀/Results</u>	<u>Toxicity Category</u>	<u>MRID</u>
Acute Dermal Toxicity/OPPTS 870.1200	> 2,000 mg/kg		
Acute Inhalation Toxicity/OPPTS 870.1300	> 4.4 mg/L	IV	448735-05
Acute Eye Irritation/OPPTS 870.2400	Ocular irritation cleared within 72 hrs.	III	448735-04
Acute Dermal Irritation/OPPTS 870.2500	Not a dermal irritant	IV	448735-03
Skin Sensitization/OPPTS 870.2600	Not a sensitizer	IV	448735-06

Test substance was 53 % Mono and Di-potassium phosphite.

Required sub-chronic mammalian toxicity data are not being referenced for lack of citable data.

Non-Target Organisms:

<u>Study Type/OPPTS Guideline</u>	<u>LD₅₀/LC₅₀/Results</u>	<u>Toxicity Category</u>	<u>MRID</u>
Avian Acute Oral/OPPTS 850.2100	> 2,000 mg/kg	Slightly toxic	448735-08
Avian Dietary/OPPTS 850.2200	> 5,000 ppm	IV	448735-09
Freshwater Invertebrate/OPPTS 850.1010	> 1,200 mg/L	Practically non-toxic	448735-11
Freshwater Fish LC50/OPPTS 850.1075	> 790 mg/L	IV	448735-10
Non-target Plants/OPPTS 850.4100	Not addressed		
Non-target Insects 850.3020	Not addressed		

Test substance was 53 % Mono- and di-potassium phosphite, 12.2 % phosphorus, 28 % phosphorous.

cc: Clara Fuentes, RAL Leonard Cole, BPPD Chron File, IHAD/ARS FT, PY-S: 02/04/2014.

CONFIDENTIAL APPENDIX

Pages 74-75 Manufacturing process information may be entitled to confidential treatment

DATA PACKAGE BEAN SHEET

Date: 17-Dec-2013

Page 1 of 2

Decision #: 483282

DP #: (416738)

PRIA

Parent DP #:

Submission #: 941168

E-Sub #:

*** Registration Information ***

Registration: **83416-1 - RELIANT SYSTEMIC FUNGICIDE**

Company: 83416 - QUEST PRODUCTS L.L.C.

Risk Manager: RM 91 - Andrew Bryceland - (703) 308-6928 Room# PY1 S-8873

Risk Manager Reviewer: Leonard Cole LCOLE02

Sent Date: _____

PRIA Due Date: 19-May-2014

Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (B681) AMENDMENT; UNREGISTERED SOURCE OF ACTIVE INGREDIENT; REQUIRES DA1

Ingredients: 076416, Mono- and di- potassium salts of phosphorous acid(45.8%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 17-Dec-2013

Due Back: _____

DP Ingredient: 076416, Mono- and di- potassium salts of phosphorous acid

DP Title: PC To Support Unregistered Source

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #: _____

Assigned To

Date In

Date Out

Organization: BPPD / BPB

Last Possible Science Due Date: 20-Nov-2013

Team Name: RM 91

Science Due Date: _____

Reviewer Name: Clara

Sub Data Package Due Date: _____

Contractor Name: _____

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

No Additional Data Packages

*** Data Package Instructions ***

Attention Russell Jones, Ph.D.: Russ, please assign this data package to one of your reviewers. The registrant has submitted product chemistry data to support an unregistered source of active ingredient. The PRIA due date is May 19, 2014. It is due back to me April 1, 2014. Thanks Russ!

MRID	MRID #	Citation Reference	Guideline	Pass/Fail
49216801		Rosenwasser, R.; Howarth, J. (2013) Reliant Systemic Fungicide: Mono- and Di- Potassium Salts of Phosphorous Acid Product Identity and Composition and Analysis (Group A). Project Number: RELIANT/13/02. Unpublished study prepared by Enviro Tech Chemical Services, Inc. 35p.	830.1550/Product Identity and composition	Pass (23-Sep-2013)
49216801		Rosenwasser, R.; Howarth, J. (2013) Reliant Systemic Fungicide: Mono- and Di- Potassium Salts of Phosphorous Acid Product Identity and Composition and Analysis (Group A). Project Number: RELIANT/13/02. Unpublished study prepared by Enviro Tech Chemical Services, Inc. 35p.	830.1600/Description of materials used to produce the product	Pass (23-Sep-2013)
49216801		Rosenwasser, R.; Howarth, J. (2013) Reliant Systemic Fungicide: Mono- and Di- Potassium Salts of Phosphorous Acid Product Identity and Composition and Analysis (Group A). Project Number: RELIANT/13/02. Unpublished study prepared by Enviro Tech Chemical Services, Inc. 35p.	830.1620/Description of production process	Pass (23-Sep-2013)
49216801		Rosenwasser, R.; Howarth, J. (2013) Reliant Systemic Fungicide: Mono- and Di- Potassium Salts of Phosphorous Acid Product Identity and Composition and Analysis (Group A). Project Number: RELIANT/13/02. Unpublished study prepared by Enviro Tech Chemical Services, Inc. 35p.	830.1650/Description of formulation process	Pass (23-Sep-2013)
49216801		Rosenwasser, R.; Howarth, J. (2013) Reliant Systemic Fungicide: Mono- and Di- Potassium Salts of Phosphorous Acid Product Identity and Composition and Analysis (Group A). Project Number: RELIANT/13/02. Unpublished study prepared by Enviro Tech Chemical Services, Inc. 35p.	830.1670/Discussion of formation of impurities	Pass (23-Sep-2013)
49216801		Rosenwasser, R.; Howarth, J. (2013) Reliant Systemic Fungicide: Mono- and Di- Potassium Salts of Phosphorous Acid Product Identity and Composition and Analysis (Group A). Project Number: RELIANT/13/02. Unpublished study prepared by Enviro Tech Chemical Services, Inc. 35p.	830.1700/Preliminary analysis	Pass (23-Sep-2013)
49216801		Rosenwasser, R.; Howarth, J. (2013) Reliant Systemic Fungicide: Mono- and Di- Potassium Salts of Phosphorous Acid Product Identity and Composition and Analysis (Group A). Project Number: RELIANT/13/02. Unpublished study prepared by Enviro Tech Chemical Services, Inc. 35p.	830.1750/Certified limits	Pass (23-Sep-2013)
49216801		Rosenwasser, R.; Howarth, J. (2013) Reliant Systemic Fungicide: Mono- and Di- Potassium Salts of Phosphorous Acid Product Identity and Composition and Analysis (Group A). Project Number: RELIANT/13/02. Unpublished study prepared by Enviro Tech Chemical Services, Inc. 35p.	830.1800/Enforcement analytical method	Pass (23-Sep-2013)
49216802		Howarth, J. (2013) Reliant Systemic Fungicide: Mono- and Di- Potassium Salts of Phosphorous Acid Physical & Chemical Properties (Group B). Project Number: RELIANT/13/02. Unpublished study prepared by Enviro Tech Chemical Services, Inc. 13p.	830.6302/Color	Pass (23-Sep-2013)
49216802		Howarth, J. (2013) Reliant Systemic Fungicide: Mono- and Di- Potassium Salts of Phosphorous Acid Physical & Chemical Properties (Group B). Project Number: RELIANT/13/02. Unpublished study prepared by Enviro Tech Chemical Services, Inc. 13p.	830.6303/Physical state	Pass (23-Sep-2013)

MRID	MRID Status	Citation Reference	Guideline	88-5 Status
49216802		Howarth, J. (2013) Reliant Systemic Fungicide: Mono- and Di- Potassium Salts of Phosphorous Acid Physical & Chemical Properties (Group B). Project Number: RELIANT/13/02. Unpublished study prepared by Enviro Tech Chemical Services, Inc. 13p.	830.6304/Odor	Pass (23-Sep-2013)
49216802		Howarth, J. (2013) Reliant Systemic Fungicide: Mono- and Di- Potassium Salts of Phosphorous Acid Physical & Chemical Properties (Group B). Project Number: RELIANT/13/02. Unpublished study prepared by Enviro Tech Chemical Services, Inc. 13p.	830.6314/Oxidizing or reducing action	Pass (23-Sep-2013)
49216802		Howarth, J. (2013) Reliant Systemic Fungicide: Mono- and Di- Potassium Salts of Phosphorous Acid Physical & Chemical Properties (Group B). Project Number: RELIANT/13/02. Unpublished study prepared by Enviro Tech Chemical Services, Inc. 13p.	830.6317/Storage stability	Pass (23-Sep-2013)
49216802		Howarth, J. (2013) Reliant Systemic Fungicide: Mono- and Di- Potassium Salts of Phosphorous Acid Physical & Chemical Properties (Group B). Project Number: RELIANT/13/02. Unpublished study prepared by Enviro Tech Chemical Services, Inc. 13p.	830.7000/pH	Pass (23-Sep-2013)
49216802		Howarth, J. (2013) Reliant Systemic Fungicide: Mono- and Di- Potassium Salts of Phosphorous Acid Physical & Chemical Properties (Group B). Project Number: RELIANT/13/02. Unpublished study prepared by Enviro Tech Chemical Services, Inc. 13p.	830.7100/Viscosity	Pass (23-Sep-2013)
49216802		Howarth, J. (2013) Reliant Systemic Fungicide: Mono- and Di- Potassium Salts of Phosphorous Acid Physical & Chemical Properties (Group B). Project Number: RELIANT/13/02. Unpublished study prepared by Enviro Tech Chemical Services, Inc. 13p.	830.7220/Boiling point/boiling range	Pass (23-Sep-2013)
49216802		Howarth, J. (2013) Reliant Systemic Fungicide: Mono- and Di- Potassium Salts of Phosphorous Acid Physical & Chemical Properties (Group B). Project Number: RELIANT/13/02. Unpublished study prepared by Enviro Tech Chemical Services, Inc. 13p.	830.7300/Density/relative density	Pass (23-Sep-2013)

45 Day Technical Screen

Date: 12/4/13

Review Date: 12/4/13

File Symbol No.: 83416-1

Reviewers: Chris Pfeifer/Russ Jones

BPB/MPB: BPB

Comments: B681 (Amendment w/ Data).

Pass/Fail: Pass

Hours Worked: 1

	Checklist Item	Yes	No	N/A	Comments
1.	Forms				
a.	8570-1: Application for Registration	y			
b.	8570-4: CSF	y			
c.	8570-27: Formulator's Exemption			na	
d.	8570-34: Certification with Respect to Data	y			Selective/OTP
e.	8570-35: Data Matrix Are any of the data that you are citing compensable? Has an Offer To Pay been made? Is documentation of said offer included in this application (Refer to 40 CFR 152.86 Cite All Method and/or 152.90 Selective Method)?	y			
2.	Data Matrix-MP or EP				
a.	Separate data matrix for the product If the study(ies) listed states "conditionally required" (CR), read the data table's footnotes to determine if is required.		n		
b.	All product chemistry/product analysis data requirements addressed (guideline by guideline; Refer to Prod Chem data table 40 CFR 158.2030).	y			
c.	All mammalian/human health toxicology/ pathogenicity data requirements addressed (guideline by guideline; Refer to Human Health data table 40 CFR 158.2050).	y			
d.	All Tier 1 nontarget organism toxicology/ pathogenicity data requirements addressed <i>plants / insects</i> (guideline by guideline; Refer to Nontarget data table 40 CFR 158.2060).	y			

Nontarget Pkn

Revised

e.	Efficacy data must be submitted and included on the data matrix for the EP if claims are being made for public health pests on the product's label.			na	
f.	HSRB review required?		n		
3.	Data Requirements-Guideline Studies			na	
4.	Label	y			
a.	Restricted Use Pesticide statement (If applicable)		n		
b.	Product name, brand or trademark	y			
c.	Ingredient statement correct? Microbial: strain designation Microbial: potency designation	y			
d.	"Keep Out of Reach of Children" (KOOROC) Statement	y			
e.	Signal word	y			
g.	Net contents/net weight	y			
h.	EPA Reg. No. and Establishment No.	y			
i.	Company name and address	y			
j.	Precautionary statement: hazards to human and domestic animals Microbial: dusk mask statement	y			
k.	Environmental hazards	y			

21-Day Screen of Amendment
(Completed by Contractor)

21-day Expires on 10/8/13

Document Part Of: 83416-1
MRID, If Any: 492168

Content Screen: Recommended to
Pass/Fail

11-3 Review: Passed/Failed/NA

Overall Status: Pass/Fail

Document returned to:

Andrew Bayceland



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

September 20, 2013

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-483282
EPA File Symbol or Registration Number: 83416-1
Product Name: RELIANT SYSTEMIC FUNGICIDE
EPA Receipt Date: 17-Sep-2013
EPA Company Number: 83416
Company Name: QUEST PRODUCTS L.L.C.

ROBERT ROSENWASSER
RR CONSULTING SERVICES, INC.
QUEST PRODUCTS L.L.C.
11712 230th STREET
LINWOOD, KS 66052

SUBJECT: Receipt of Amendment and 75% Small Business Waiver Request

Dear Registrant:

The Office of Pesticide Programs has received your amendment, 75% small business waiver request, and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: B681

AMENDMENT;UNREGISTERED SOURCE OF ACTIVE INGREDIENT;REQUIRES DATA
SUBMISSION;

Your request for waiver has been forwarded for review. You will be notified in writing when a determination is made regarding your request. If your waiver request is approved, the decision review time period will start on the date of approval. If your waiver request is denied, you will receive an invoice for the outstanding balance.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-0152.

Sincerely,

A handwritten signature in black ink, appearing to be "m sh", is written over the word "Sincerely,".

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{941168:~

This package includes the following

- ☐ New Registration
- ☒ Amendment

☒ Studies? ☐ Fee Waiver?
☐ volpay % Reduction: ____

for Division

- ☐ AD
- ☒ BPPD
- ☐ RD

Risk Mgr. 91

Receipt No.

S-

941168

EPA File Symbol/Reg. No.

83416-1

Pin-Punch Date:

9/17/2013

☐ This item is NOT subject to FFS action.

Action Code:

Requested:

B681

Granted:

B681

Amount Due: \$ _____

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: Andrew Byrdland

Date: 9/20/13

Remarks:



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

September 19, 2013

**OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION**

RR CONSULTING SERVICES, INC.
QUEST PRODUCTS L.L.C.
273 ALTHEA AVENUE
MORRISVILLE, PA 19067

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 17-SEP-13. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Receipt for Section 3

S: 941168	Resubmission: <input type="radio"/> Yes <input checked="" type="radio"/> No	<input type="button" value="Print Letter"/> <input type="button" value="Enter More Information"/> <input type="button" value="Tracking"/>	
Regulatory Type: Product Registration - Section 3	Fee For Service: <input checked="" type="radio"/> Yes <input type="radio"/> No		
Application Type: Amendment	Billable: <input checked="" type="radio"/> Yes <input type="radio"/> No		
Company: 83416 QUEST PRODUCTS L.L.C.	<input checked="" type="checkbox"/>		
Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91			
Product #: 83416-1	Product Name: RELIANT SYSTEMIC FUNGICIDE		
Override#:			
Me Too Section3:	Me Too Product Name:		
Application Date: 16-Sep-2013 <input checked="" type="checkbox"/>	OPP Rec'd Date: 17-Sep-2013 <input checked="" type="checkbox"/>	<input type="button" value="Receipt Content"/> <input type="button" value="Study"/> <input type="button" value="CSF"/> <input type="button" value="View/Edit"/>	
Front End Date: 18-Sep-2013 <input checked="" type="checkbox"/>	Risk Manager Send Date:		
FFS Due Date:	Negotiated Due Date:		
OPP Target Date:			
Fast Track: <input type="checkbox"/>	New Ingredient: <input type="checkbox"/>		
Receipt Description:			
Adding source of unregistered of active ingredient and proposing allowing manufacturing the product instead of 100% repack.		New Ingredient Request Date: New Ingredient Received Date: 	
Form A: <input type="checkbox"/>	Signature Date:	Form B: <input type="checkbox"/>	Signature Date:

Deco# 483292

B682

FFS start: 10/17/13

PAIA due 5/15/14

1-15-14

3/7

FEB 2 2014

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 9/17/13

Experts In-Processing Signature: MP Date 9/20/13

Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date

EPA Reg. Number: <u>83416-1</u>		EPA Receipt Date: <u>9/17/13</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
	<i>* No inerts to review</i>					
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)			X		
7	Is the data package consistent with PR Notice 86-5			X		
8	Notice of Filing included with petitions					X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
	<u>Required Data</u> and/or data waivers. See Footnote C.			
10	a) List study (or studies) not included with application			

Comments:

- * submitted study PASSED PEN 11-3 review
- * Technical + Impurities only — no merits to review
- * Amendment turned in late due to shutdown
- * Amendment PASSED

YFC

MRID: 442108

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the inert Web site and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch.

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



49216800

11712 230th St
Linwood, Kansas 66052
Phone 785-542-2577
Fax 785-542-2531

September 16, 2013

Document Processing Desk (AMEND)
Office of Pesticide Programs (7511P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

ATTN: Linda Hollis, BPPD

RE: RELIANT SYSTEMIC FUNGICIDE, EPA Reg. No. 83416-1
Amendment to add an unregistered source of active ingredient
PRIA Code B681

Quest Products LLC., 11712 230th Street, Linwood, KS 66052, is submitting this application to add an unregistered source of supply of the active ingredient, Mono- and di- potassium salts of phosphorous acid, to the registration.

The registrant is proposing to amend its 100% Repack registration to allow the company to manufacture the product instead of repackaging an EPA-registered product.

Accordingly, this amendment is filed as PRIA Action Code B681. It contains data to add an alternate formulation. These data include toxicity data, non-target toxicity data and product chemistry data to support the unregistered source of the active ingredient with (manufacturing process, etc.).

Earlier communications with Gia Burnett, Acting Team Leader, Biochemical Pesticides Branch (BPB), Biopesticides and Pollution Prevention Division (BPPD), indicated that EPA will allow this change as a B681 if all data requirements are satisfied in the submission and the new end-use product formulation is identical to the existing registered B660 formulation (with the only difference being the source of the AI).

As a result of the addition our own source of AI, Reliant Systemic Fungicide would no longer qualify as a repack. According to EPA's *100% Repacks: Guidance on Alternate Formulations and Allowable Uses*, March 24, 2010, the product would no longer qualify as a 100% repack. With the inclusion of required data to sustain the amendment, Quest Products LLC requests that the current registration be transformed or upgraded from repack to full primary status as a result of this amendment. Guidance on this path to primary status was also offered by Gia Burnett.

At this time, an amended product label is also being submitted for additional uses. Any proposed changes to the label require no additional data for review. The active ingredient, Mono- and di- potassium salts of phosphorous acid, is exempt from tolerance (40 CFR 180.1200).

Quest Products LLC is complying with the data compensation requirements under the selective method of support by listing the specific data requirements that apply to our product (its active ingredients and/or use patterns) and by demonstrating compliance with the data requirements by citing individual studies.

Quest Products LLC will be citing (with an Offer to Pay) required data for acute toxicity, acute aquatic toxicity, freshwater, invertebrate acute toxicity, freshwater, avian dietary toxicity and avian acute oral toxicity. Certification with Respect to Citation of Data form is included.

Regarding other data requirements, Quest Products LLC is requesting waivers per 40 CFR §158.45. The rationale for the data request stems from our inability to find submitters of the required data. More importantly, it appears that existing registrants for products containing Mono- and di- potassium salts of phosphorous acid as the sole active ingredient have requested data waivers. The lack of citable data appears to mean these waiver requests were likely approved.

The submitted Data Matrix indicates which requirement for which a waiver was requested. A separate waiver matrix is provided which details the submission of all waiver requests versus guideline requirements. The waiver requests are not studies. As a result, Quest Products LLC believes it has shown that no studies have been previously submitted to the Agency.

Included with this application are:

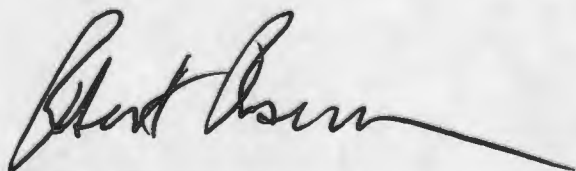
- Completed application for registration;
- PRIA Fee (B681) of \$1,379 (reduced)
- Pesticide Registration Fee Waiver Form;
- Six copies of the amended label;
- Three copies of Product Chemistry Group A (including CSF);
- Three copies of Product Chemistry Group A Confidential Appendix;
- Three copies of Product Chemistry Group B;
- One loose copy of the Confidential Statement of Formula;
- Certification with Respect to Citation of Data;
- Data Matrix;
- Data Matrix, public copy and;
- Waiver Matrix.

49216801

49216802

If you have any questions or need any additional information, please to contact me at (215) 715-6419 or <mailto:rrosenwasser@verizon.net>.

Sincerely,



Robert Rosenwasser
Agent for Quest Products, LLC



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director: OPPE Information Management Division (2137) U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date September 16, 2013

EPA Reg. No./File Symbol 83416-1

Page 1 of 3

Applicant's/Registrant's Name & Address:

Quest Products LLC, 11712 230th St., Linwood, KS 66052

Product

RELIANT SYSTEMIC FUNGICIDE

Ingredient Mono- and di- potassium salts of phosphorous acid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830-1550	Product identification and composition	submitted	Quest Products LLC		
830-1600	Description of materials used to produce product	submitted	Quest Products LLC		
830-1620	Beginning materials and Mfg. process	submitted	Quest Products LLC		
830-1650	Description of Formulation Process	submitted	Quest Products LLC		
830-1670	Formation of Impurities	submitted	Quest Products LLC		
830-1700	Preliminary analysis	submitted	Quest Products LLC		
830-1750	Certified limits	submitted	Quest Products LLC		
830-1800	Enforcement analytical method	submitted	Quest Products LLC		
830-6302	Color	submitted	Quest Products LLC		
830-6303	Physical state	submitted	Quest Products LLC		
830-6304	Odor	submitted	Quest Products LLC		
830-6313	Stability	submitted	Quest Products LLC		
830-6314	Oxidizing or reducing action	submitted	Quest Products LLC		
830-6315	Flammability	waiver	Product does not contain any combustible liquids.		
830-6317	Storage stability	To be submitted	Quest Products LLC		
830-6319	Miscibility	waiver	Product is not an emulsifiable liquid and is not to be diluted with petroleum solvents.		



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date September 16, 2013			EPA Reg. No./File Symbol 83416-1	Page 2 of 3	
Applicant's/Registrant's Name & Address: Quest Products LLC, 11712 230 th St., Linwood, KS 66052			Product RELIANT SYSTEMIC FUNGICIDE		
Ingredient Mono- and di- potassium salts of phosphorous acid					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830-6320	Corrosion characterization	To be submitted	Quest Products LLC		
830-7000	pH	submitted	Quest Products LLC		
830-7100	Viscosity	submitted	Quest Products LLC		
830-7220	Boiling point/range	submitted	Quest Products LLC		
830-7300	Density	submitted	Quest Products LLC		
830-7950	Vapor pressure	waiver	Not required for salts		
850-1010	Invertebrate acute toxicity, freshwater	44873511	JH Biotech	Offer to pay	
850-1075	Freshwater acute toxicity	44873510	JH Biotech	Offer to pay	
850-2100	Avian acute oral toxicity	44873508	JH Biotech	Offer to pay	
850-2200	Avian dietary toxicity	44873509	JH Biotech	Offer to pay	
870-1100	Acute toxicity - Oral	44873501	JH Biotech	Offer to pay	
870-1200	Acute toxicity - Dermal	44873502	JH Biotech	Offer to pay	



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401 M Street, S.W.
WASHINGTON, D.C.

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DATA MATRIX

Date September 16, 2013

EPA Reg. No./File Symbol 83416-1

Page 3 of 3

Applicant's/Registrant's Name & Address:

Quest Products LLC, 11712 230th St., Linwood, KS 66052

Product

RELIANT SYSTEMIC FUNGICIDE

Ingredient Mono- and di- potassium salts of phosphorous acid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870-1300	Acute toxicity – Inhalation	44873505	JH Biotech	Offer to pay	
870-2400	Primary Eye Irritation	44873504	JH Biotech	Offer to pay	
870-2500	Primary Dermal Irritation	44873503	JH Biotech	Offer to pay	
870-2600	Dermal sensitization	44873506	JH Biotech	Offer to pay	
870-3100	90-day oral (one species)		Quest Products LLC	Waiver	
870-3250	90-day dermal rat		Quest Products LLC	Waiver	
870-3465	90-day inhalation rat		Quest Products LLC	Waiver	
870-3700	Prenatal developmental - rat		Quest Products LLC	Waiver	
870-5100	Bacterial reverse mutation test		Quest Products LLC	Waiver	
870-5300/5375	In vitro mammalian cell assay		Quest Products LLC	Waiver	
870-5385/5895	In vivo Mammalian Cytogenetics		Quest Products LLC	Waiver	

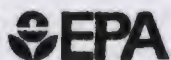
Signature

Name and Title

Robert Rosenwasser
Agent, Quest Products LLC.

Date

September 16, 2013



United States
Environmental Protection Agency
Washington, DC 20460

☐
☒
☐

Registration
Amendment
Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 83416-1	2. EPA Product Manager Linda Hollis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Reliant Systemic Fungicide	PM# 90	
5. Name and Address of Applicant (Include ZIP Code) Quest Products LLC. 11712 230th Street Linwood, KS 66052 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Amendment to add an unregistered source of active ingredient
PRIA Code B681

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Robert Rosenwasser		Title Agent, Quest Products LLC.	
		Telephone No. (Include Area Code) 215-715-6419	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title Agent, Quest Products LLC.	
4. Typed Name Robert Rosenwasser		5. Date September 16, 2013	



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1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Quest Products LLC., 11712 230th St., Linwood, KS 66052, 785-542-2577	EPA Registration Number/File Symbol 83416-1
Active Ingredient(s) and/or representative test compound(s) Mono- and di- potassium salts of phosphorous acid	Date September 16, 2013
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial food, terrestrial non-food, greenhouse food, greenhouse non-food, forestry	Product Name Reliant Systemic Fungicide

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
--	---

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature 	Date 9-16-13	Typed or Printed Name and Title R. Rosenwasser, Agent, Quest Products, LLC
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Applicant's/Registrant's Name & Address:

Quest Products LLC, 11712 230th St., Linwood, KS 66052

Product

RELIANT SYSTEMIC FUNGICIDE

Ingredient Mono- and di- potassium salts of phosphorous acid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Quest Products LLC		
			Quest Products LLC		
			Quest Products LLC		
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			Quest Products LLC		

Quest Products LLC



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Date September 16, 2013

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Page 2 of 3

Applicant's/Registrant's Name & Address:Quest Products LLC, 11712 230th St., Linwood, KS 66052**Product**

RELIANT SYSTEMIC FUNGICIDE

Ingredient Mono- and di- potassium salts of phosphorous acid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Quest Products LLC		
			Quest Products LLC		
			Quest Products LLC		
			Quest Products LLC		
			Quest Products LLC		



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Applicant's/Registrant's Name & Address:

Quest Products LLC, 11712 230th St., Linwood, KS 66052

Product

RELIANT SYSTEMIC FUNGICIDE

Ingredient Mono- and di- potassium salts of phosphorous acid

Guideline Reference Number

Guideline Study Name

MRID Number

Submitter

Status

Note

Signature

Name and Title

Robert Rosenwasser
Agent, Quest Products LLC.

Date

September 16, 2013

WAIVER MATRIX

WAIVER MATRIX				
Date September 16, 2013			EPA Reg. No. 83416-1	
Registrant's Name & Address: Quest Products LLC, 11712 230 th St., Linwood, KS 66052			Product RELIANT SYSTEMIC FUNGICIDE	
Ingredient Mono- and di- potassium salts of phosphorous acid				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Rationale* (See note below)
870-3100	90-day oral (one species)	46708219 47760831 48193403 48498513	Actagro, Plant Protectants Winfield Luxembourg-Pamol	Waiver-An exemption from the requirement of a tolerance is established for residues of phosphorous acid and its ammonium, sodium and potassium salts in or on all food commodities when used as an agricultural fungicide on food crops. (40 CFR 180.1200)
870-3250	90-day dermal rat	46645802 46708219 47760832 48193403	Biagro Western Sales Actagro Plant Protectants Winfield	Waiver-No purposeful application to the human skin or which would result in comparable prolonged human exposure to the product.
870-3465	90-day inhalation rat	46645803 46708219 47760833 48193403	Biagro Western Sales Actagro Plant Protectants Winfield	Waiver-There is little likelihood of significant levels of repeated inhalation exposure to the pesticide as a gas, vapor, or aerosol.
870-3700	Prenatal developmental - rat	47760834 48193403 48498513	Plant Protectants Winfield Luxembourg-Pamol	Waiver-Product under widespread and commonly recognized practice may not reasonably be expected to result in significant exposure to female humans (e.g., occupational exposure).
830-7200	Bacterial reverse mutation test	47760837 48193403	Plant Protectants Winfield	Waiver
870-5300/5375	In vitro mammalian cell assay	47760837 48193403 48498513	Plant Protectants Winfield Luxembourg-Pamol	Waiver-The active ingredient (or its metabolites) is not structurally related to a known mutagen or belongs to any chemical class of compounds containing a known mutagen.
870-5385/5895	In vivo Mammalian Cytogenetics	48498513	Luxembourg-Pamol	Waiver

* Waiver rationale for each guideline requirement is not limited to what is stated or reflect the reasoning made to request and secure each waiver.

27.27.00

PH. 785-542-2577
11712 230TH ST.
LINWOOD, KS 66052

5276

DATE 9.5.2013



PAY TO THE
ORDER OF__

PAY TO THE ORDER OF U.S. Environmental Protection Agency \$ 1379.00

One thousand three hundred seventy nine + 1000 DOLLARS



Kaw Valley Bank

739 MAIN
EUDORA, KANSAS 66025 #83416-1


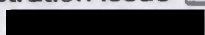
MEMO

Update Reliant Systemic
Ergicide label

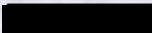
Paula M. Hingelberg


Security Feature
Included
Details on Back.



Re: EPA Registration issue 
Linda Hollis to: 

05/30/2012 11:51 AM


Dear 

As discussed with you over the phone, I have looked into the case file for the competitive product Reliant Systemic Fungicide, EPA Reg No. 83416-1, registered on March 22, 2012. As expected, the Agency did not make any errors with regard to issuing this registration. The application was submitted as a 100 percent repack of your product . To qualify as a repacked product, certain forms need to be submitted. These forms include: application for registration, a formulator's exemption form and a confidential statement of formula which explicitly states that the product is a 100% repack of another product. All of the above forms were submitted. In addition, the product labeling does not contain any additional use sites, which would not be allowed under a repack registration.


Therefore, I am afraid, as I eluded to over the phone, that your case is of a matter that you may or may not elect to investigate any further as the EPA was not in error in issuing the registration for the above product.

Linda A. Hollis, MS
Chief, Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs (7511P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202
hollis.linda@epa.gov
(703) 308-8733 (phone)
(703) 308-7026 (fax)
Visit <http://www.epa.gov/pesticides>

"The journey of 1000 miles begins with one step.....Take the step"

 Linda, Thank you for your time this morning.

05/23/2012 03:55:06 PM

From: 
To: Linda Hollis/DC/USEPA/US@EPA
Date: 05/23/2012 03:55 PM
Subject: EPA Registration issue

Linda,
Thank you for your time this morning.
Attached is a letter requesting that EPA investigate and cancel the re-pack registration for Reliant Fungicide due to the fact that Quest Products does not have our permission to do so.

Also attached is a letter that was sent to EPA before Reliant was officially registered.

Product ingredient source information may be entitled to confidential treatment

If you check the labels for Reliant and [REDACTED] you will see that they are the same label.

To me this is no more than an attempt to steal our registration and I believe that this is not the intent of EPA to allow this type of activity.

Please contact me as soon as possible to let us know what we need to do to get re-pack registration canceled.

Thank you,

[REDACTED]

